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, 2021

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.)**
200 Forge Way, Suite 205, Rockaway, NJ	07866
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.001 Per Share	**ECOR**	**Nasdaq Global Select Stock Market**

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2021 was $51,984,860.

The number of shares of Registrant’s Common Stock outstanding as of March 1, 2022 was 70,718,191.

Portions of the Registrant’s Definitive Proxy Statement relating to the 2022 Annual Meeting of Stockholders, which will be filed with the Securities Exchange Commission within 120 days after the end of the Registrant’s fiscal year ended December 31, 2021, are incorporated by reference into Part III of this Report.

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Cautionary Note Regarding Forward-Looking Statements

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

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

References to electroCore

In this Annual Report, unless otherwise stated or the context otherwise indicates, references to “ECOR,” “electroCore,” “the Company,” “we,” “us,” “our” and similar references refer to electroCore, Inc., a Delaware corporation.

Risk Factor Summary

The following is a summary of certain important factors that may make an investment in our Company speculative or risky. You should carefully consider the full risk factor disclosure set forth in Item 1A of this Annual Report, in addition to the other information herein, 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.

- The coronavirus pandemic could have a significant negative impact on our business, revenues, financial condition and results of operations.
- 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 will be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all.
- Commercializing our gammaCore Sapphire CV therapy for the acute treatment of asthma exacerbations in known or suspected COVID-19 patients may require targeted investment in research and development and expansion of our sales and marketing capabilities.
- We rely upon specialty pharmacies to distribute some of our products in the United States.
- Regulatory requirements and changes to payers’ prescription benefit plans and medical pathway plans could adversely impact our business and financial results.
- We must demonstrate to patients, physicians and third-party payers the medical and economic benefits of our gammaCore therapy compared to those of our competitors or other available therapies and such comparisons may not be realizable.
- Our operating results may vary significantly from quarter to quarter because of seasonality, bulk orders, shipments to distributors or otherwise.
- Commercialization of our gammaCore Sapphire therapy for additional neurological conditions may require clinical trials that are very expensive, time-consuming, 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, clinical trials or commercial success.
- If we fail to develop and retain an effective sales and customer service function, our business could suffer.
- We recently launched new cash pay initiatives, including our gConcierge and gCDirect programs, and patients and providers may be slow to adopt these programs or their pricing which could adversely impact our business and financial results.

- If our competitors are better able to develop and market primary headache treatments that are safer, more effective, less costly, easier to use or otherwise more attractive than our gammaCore therapy, our business and business prospects will be adversely impacted.
- Many of our competitors are large, well-established companies with substantially greater resources than us and have a long history of competing in the migraine market.
- Traditional products used to treat cluster headache and migraine have been available for decades, while our gammaCore therapy has only been commercially available in Europe for several years, and for approximately three years in the United States, and, as a result, we have a limited track record compared to our competitors.
- Our international operations subject us to certain operating and compliance risks, which could adversely impact our results of operations and financial condition.
- We may not be able to establish or strengthen our brand.
- We relied upon primary, secondary, and sole source third-party suppliers located in China and elsewhere for components and packaging of our gammaCore products, which suppliers have paused delivery at our request, thereby making us vulnerable to supply shortages, price fluctuations, and an inability to reactivate supply chains, if necessary, all of which could harm our business.
- Our potential revenue in the United Kingdom is substantially dependent on government funding arrangements and changes in such governmental policy could cause material harm to our business.
- 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 other countries and to expand the use of our gammaCore therapy to additional therapeutic indications.
- Our failure to meet the continued listing requirements of Nasdaq could result in delisting of our common stock, which could negatively impact the market price and liquidity of our common stock and our ability to access the capital markets.
- We are currently subject to securities class action lawsuits against us, which could result in adverse outcomes.
- Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.
- 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.
- 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.

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, and/or 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.

PART I

Item 1. Business

Business Overview

We are a commercial stage medical device company with a proprietary non-invasive vagus nerve stimulation, or nVNS, therapy, called gammaCore. nVNS is a platform bioelectronic medical therapy that modulates neurotransmitters and immune function through its effects on both the peripheral and central nervous systems. We are initially focused on utilizing gammaCore in the management and treatment of primary headache conditions, but we believe our nVNS therapy may be used in the future to effectively treat other medical conditions with studies ongoing in stroke, post-traumatic stress disorder, and opioid withdrawal among others.

gammaCore is the first prescription-only nVNS therapy cleared by the Food and Drug Administration ("FDA"). Historically, vagus nerve stimulation, or VNS, required an invasive surgical procedure to implant a costly medical device which presents an infection risk. These limitations have generally limited VNS from being used by anyone other than the most severe patients. Our lead product, gammaCore Sapphire, is a simple-to-use handheld device intended for regular or intermittent use over many years.

Our gammaCore Sapphire delivers non-invasive VNS through a proprietary high-frequency burst waveform that safely and comfortably passes through the skin and stimulates therapeutically relevant fibers in the vagus nerve. Multiple published studies suggest that VNS works through a number of mechanistic pathways including the modulation of neurotransmitters and has a measurable effect similar to several classes of commonly prescribed medications.

Since our inception, we have sought regulatory approvals to market our novel product in the United States and abroad. As we have obtained initial and additional regulatory approvals, we have implemented commercial strategies to target an expanding base of potential patients.

U.S. Regulatory Clearances

gammaCore, is cleared by the FDA for use in the following indications:

- the acute treatment of pain associated with each of migraine headache and episodic cluster headache in adults, or eCH;
- the preventive treatment of migraine headache and adjunctive use for the preventive treatment of cluster headache in adults, or CH;
- the acute and preventive treatment of migraine in adolescents between 12 and 17 years of age; and
- the treatment of Paroxysmal Hemicrania, or PH, and Hemicrania Continua, or HC, in adults.

We are also considering several additional indications for our nVNS technology which are being studied in a number of investigator-initiated trials, or IITs. These indications include post-traumatic headache, stroke, mild traumatic brain injury, post-traumatic stress disorder, sub-arachnoid hemorrhage, opioid use disorders, symptoms of Parkinson's disease, post-operative ileus and gastroparesis.

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

In January 2022, the FDA granted gammaCore Sapphire ‘Breakthrough Device designation for the treatment of post-traumatic stress disorder or PTSD’. PTSD is a highly prevalent and disabling disorder with limited approved treatment options.

UK and European Regulatory Clearances

We received a CE Certificate of Conformity for gammaCore for the treatment of primary headache from the British Standards Institution, a European Union notified body. This CE Certificate of Conformity allowed us to affix the CE Mark on gammaCore and to commercialize it in the European Economic Area and other countries that recognize the CE Mark. In addition, we received CE Certificates of Conformity on gammaCore covering four other indications for use, including reactive airway disease and gastric motility disorders.

In 2019, the National Institute for Health and Care Excellence, or NICE, published a Medical Technology Guidance document recommending the use of gammaCore for CH within National Health Service, or NHS, of England and Wales. In January 2021, NHS Scotland adopted the NICE recommendation and recommended gammaCore for use in treatment of CH in Scotland.

NHS England awarded gammaCore a place on the Innovation Technology Payment, or ITP, program for treatment of patients with refractory (severe) cluster headache, a reimbursement pathway that opened in April 2019. In October 2020, we announced that the ITP was extended through March 2021. Effective April 1, 2021, gammaCore Sapphire was included in a new long-term reimbursement policy, the MedTech Funding Mandate Policy 2021/22, or MTFM.

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 important biochemicals including norepinephrine, cyclo-oxygenase, calcitonin gene-related peptide, acetylcholine, glutamate, serotonin, and gamma-Aminobutyric acid. The release of these substances, which have been the targets of numerous pharmaceutical agents, have been identified as therapeutic for the treatment of multiple conditions, including epilepsy, depression and headache.

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

Our Therapy Delivery Platform

Our gammaCore therapy is prescription-only, with patients self-administering discrete doses using a handheld unit. Our flagship model, gammaCore Sapphire is a portable, reusable, rechargeable and reloadable option for patients, with the prescription being written by a health care provider and dispensed from a specialty pharmacy, through the patient’s healthcare system, or fulfilled from our facility in Rockaway, NJ. After the initial prescription is filled, access to additional therapy can be refilled for certain of our gammaCore Sapphire products periodically through the input of a prescription-only authorization code. This code is currently delivered in the form of a radio-frequency identification, or RFID, card (similar to a credit card or hotel keycard), dispensed by mail from a specialty pharmacy distribution partner, or fulfilled by the Company directly to certain patients. The Company also provides a validated cleaning and disinfection protocol allowing Sapphire devices to be used on multiple patients in a healthcare center or to recover and redeploy Sapphire devices in the field.

Competitive Strengths

We believe the competitive strengths of our company and nVNS therapy include:

Innovative bioelectronic medicine approach. Our gammaCore therapy uses a proprietary electrical signal to safely deliver non-invasive VNS, which can cause targeted changes in neurotransmitter expression in a manner that has been shown to have minimal side effects through clinical studies and commercial experience encompassing tens of thousands of patients.

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

We have generated significant scientific data supporting the safety and efficacy of gammaCore which has led to FDA clearances and additional global regulatory approvals for use in multiple indications. We believe our scientific data supporting the safety and efficacy of our therapy provides broader confidence in gammaCore.

Commercial arrangements in the United States. We expect that a majority of our 2022 sales of gammaCore will be made pursuant to our qualifying contract under the Federal Supply Schedule, or FSS, which was secured by us in December 2018, as well as open market sales to individual facilities within government channels. The FSS makes gammaCore available to patients managed within FSS eligible entities such as the Department of Veteran's Affairs or VA, Department of Defense or DoD, Bureau of Prisons, Indian Health Services and Public Health Services.

Commercial arrangements outside the United States. We believe our success in gaining regulatory approval and reimbursement in the UK is significant both in its potential for commercial penetration, but also its precedential value in potentially getting reimbursement in other geographic areas. Effective April 1, 2021, gammaCore Sapphire was included in a new long-term reimbursement policy in the UK. The UK MedTech Funding Mandate, or MTFM policy, supports the use of NICE-approved, clinically effective and cost-saving medical devices, diagnostics and digital technologies that will improve patient outcomes. In December 2019, NICE published a Medical Technology Guidance document recommending the use of gammaCore for CH within the NHS of England and Wales. Consequently, in January 2021, gammaCore was recommended for use in treatment of CH in NHS Scotland. Recently, we have also announced agreements with distributors to make gammaCore Sapphire available in several countries beyond the U.S. and United Kingdom.

Broad intellectual property protection. We hold more than 195 patents and patent applications, including 112 issued U.S. patents, 42 U.S. patent applications, and 45 international patents and applications that, we believe, provide broad protection of key technologies, methods and applications of our products.

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

Our Strategy

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

We have generally focused most of our sales efforts in two channels, the U.S. Department of Veterans Affairs and U.S. Department of Defense, and the United Kingdom. However, we believe there may be significant opportunities beyond these two markets. Therefore, in 2022, we plan to invest in expanded commercial adoption of gammaCore with online stores and cash pay, physician dispense, telehealth, and direct-to-consumer approaches. Key aspects of this strategy include;

- Exploiting our qualifying contract on the FSS, which we secured in December 2018, and open market sales to individual VA facilities. Veteran's Administration Headache Center of Excellence Annual Report, approximately 410,000 patients saw a VA healthcare provider for headache in 2020 and VA's National Director of the Headache Center of Excellence program has stated that the VA has approximately 29,000 cluster headache sufferers. The VA and DoD have become our primary source of U.S. revenue and, accordingly, we have redeployed most of our sales function to generating sales from this channel.

- Expanding our direct-to-consumer promotion, including the opening of telemedicine portal and online stores in the United States and United Kingdom to reach patients and their health care advisors for the prevention and treatment of primary headache disorders.

- Expanding call points from the traditional neurology headache specialists to include the wide range of medical providers who manage patients' headache conditions. Those specialties include prescribers in primary care, women's health, pain management, functional and integrative medicine, as well as chiropractors, and PharmDs (Doctors of Pharmacy).

- In the United Kingdom, continued expansion under the MTFM program for cluster headache and cash pay product offerings via the online store.

- Working towards leveraging the unique HCPCS code K1020 "non-invasive vagus nerve stimulator" that was established as part of CMS' second biannual 2020 Coding Cycle for non-drug and non-biological items and services, and which we believe could streamline reimbursement for both government and commercial payers.

- Utilizing selected distribution partners to commercialize our gammaCore therapy in territories outside of the United States and United Kingdom.

- Developing future iterations of our therapy delivery platform, including the use of our intellectual property around the delivery of smartphone-integrated and smartphone-connected non-invasive therapies.

Migraine

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

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.

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

In February 2021, gammaCore was cleared by the FDA, through a 510(k) review, for the acute and preventive treatment of migraine in adolescents between 12 and 17 years of age.

Migraine Market Factors and Competition

Migraine Prevalence and Market Size. In the United States, 39 million patients are affected by migraine, with more than 28 million being adult women. Migraine attacks can be extremely disabling and more than 90% of migraine sufferers are unable to work or function normally while experiencing migraine. According to a recent analysis, the annual economic burden of migraine in the United States is approximately $78 billion. Further, it is estimated that the annual total direct and indirect costs of all migraine-related health services are between $8,500 and $9,500 for an individual patient with chronic 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. The marketing landscape for the treatment and prevention of migraine is highly competitive.

Current Treatments for Prevention of Migraine and Their Limitations. Most migraine patients manage their conditions with over-the-counter therapies. 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. The triptan drug class is the current first line therapy 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.

Additional treatments for prevention of migraine include blood pressure-lowering medications such as beta blockers and channel blockers, antidepressants, and anti-seizure drugs. BOTOX marketed by Allergan plc, is specifically approved for the prevention of chronic, but not episodic, migraine.

There are currently several antibodies to calcitonin gene-related peptide receptor, or CGRP, and its receptor, approved by FDA for the prevention of migraine including products sold by Teva Pharmaceuticals Industries Ltd., Eli Lilly and Company, Amgen Inc., which is in a co-marketing partnership with Novartis International AG and H. Lundbeck A/S. Preventive CGRP monoclonal antibodies are large molecules, delivered once per month or per quarter as a subcutaneous injection or infusion. Gepants, on the other hand, are small molecule CGRP receptor antagonists that were initially utilized as migraine abortives but have also been approved to prevent migraine. Recently, there have been two oral Gepants that have received FDA approval for the prevention of migraine headache including Nurtec ODT (rimegepant), a Gepant sold by Biohaven Pharmaceuticals Inc.

There are a number of neuromodulation devices that have been marketed for the prevention of migraine and which may be marketed for use in treating pain associated with primary headache without a prescription. In addition, Cefaly received clearance for use to treat migraine in adolescents.

Current Acute Migraine Treatments and Their Limitations. Triptan medications, or Triptans, are a family of tryptamine-based drugs first sold in the 1990s, which account for approximately 80% of the acute prescriptions written annually for migraine. Triptans are sold in oral, nasal, and subcutaneous formulations. Through their binding to specific serotonin 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.

The FDA has approved two oral small molecule CGRP receptor antagonists for the acute treatment of migraine with or without aura in adults. These products are marketed by Allergan plc and Biohaven Pharmaceuticals Inc. The FDA has also approved Eli Lilly's lasmiditan for acute treatment of migraine in adults.

There are a number of neuromodulation devices that have been marketed for the treatment of migraine, including Cefaly and, Nerivio (sold by Theranica Bioelectronics), as well as other neuromodulation devices that may be marketed for use in treating pain associated with primary headache. Cefaly has been granted OTC clearance allowing it to be sold without a prescription and the impact of this clearance on the competitive landscape remains to be seen. Other less commonly prescribed acute migraine treatments include ergotamines and analgesics, including non-steroidal anti-inflammatory drugs, or NSAIDs, acetaminophen and antiemetics. Dihydroergotamine, or DHE, is a grain fungus derivative that, like triptans, is a potent vasoconstrictor. DHE has been used for more than 50 years for the treatment of migraine, but modern physicians rarely prescribe it because of its significant side effects. In 2021, a new DHE nasal spray was approved for the treatment of migraine. 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.

Cluster Headache

In April 2017, FDA granted our *de novo* submission, clearing our gammaCore for commercial sale in the United States for the acute treatment of pain associated with eCH in adults. In December 2018, we were successful in receiving FDA clearance for gammaCore Sapphire as a prevention for CH, the first product in the United States or Europe to receive regulatory approval for this indication.

CH is a condition in which patients experience extremely painful headache attacks that have been described by patients and physicians as some of the most painful known. CH predominantly affects males in their prime earning ages of 20 to 50, and the attacks of pain occur in bouts, known as cluster periods, during which attacks are experienced at a frequency ranging from every other day to as often as eight times per day. Individual attacks typically last from 15 minutes to as long as three hours. Among CH patients, 85% to 90% experience eCH, with their cluster periods, or bouts, lasting from two to 12 weeks, followed by a remission period, often cycling into bouts twice per year. There is only one other FDA-approved commercially available pharmaceutical option for acute CH treatment, and gammaCore is the only FDA-cleared option for the prevention of all forms of CH.

Cluster Headache Market Factors-United States

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 an estimated 400,000 patients.

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

Other Therapies for the Treatment and Prevention of Cluster Headache. Injectable sumatriptan (Imitrex) is an FDA-approved commercially available therapy for acute treatment for CH. The side effect profile and cost of Imitrex, however, usually enables patients to treat only a small fraction of their attacks each month and 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. The most frequently used acute treatments for CH attacks are subcutaneous sumatriptan and high flow rate inhaled oxygen. Alternative treatments include intranasal triptans and intravenous dihydroergotamine, or DHE. Galcanezumab, a calcitonin gene-related peptide that is produced by Eli Lilly and Company was recently approved by the FDA for the treatment of eCH.

Additional medications that are used by patients off-label include verapamil, lithium, and valproate.

Cluster Headache Market Factors - United Kingdom

Prevalence and market size. The estimated prevalence of CH in the United Kingdom ranges from 0.1% to 0.2% of the total population, with approximately 66,000 affected patients.

Economic Burden. According to the MTFM published by NHS England and NHS Improvement in January 2021, the overall cost for treating CH patients in England over the next five years will be approximately £218.7 million. 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 payments due to the disorder.

Other Therapies for the Treatment of Cluster Headache. The goal of available treatments is total attack cessation, or suppression of headache until the next episode. Therapies are prescribed in an attempt to prevent CH attacks (prophylaxis) and to manage pain at the time of a headache (acute / abortive treatment); the latter is rarely sufficient to achieve adequate control alone.

Primary Headache Market-Potential Future Market Factors

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

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

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

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

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

We 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."

Emergency Use Authorization

In July 2020, the FDA granted the Company an Emergency Use Authorization ("EUA") authorizing the use the Company's gammaCore Sapphire CV nVNS therapy at home or in a healthcare setting to acutely treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief.

We did not recognize material revenue from the sales of gammaCore Sapphire CV during the year ended December 31, 2021, and we do not expect to recognize material revenue from the sale of gammaCore Sapphire CV in general.

Manufacturing

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

At our facility in Rockaway, New Jersey, we inspect inbound component parts to ensure they meet our design and manufacturing specifications. This quality process involves physical inspection and electrical performance testing. After successful completion of this inspection, each gammaCore unit is then packaged, along with appropriate labeling, instructions for use, important safety information, an initial RFID card (when the therapy is not preloaded), and conductive gel, and shipped into our distribution network, or direct-to-end user. Additional RFID cards and conducive gels are sent at the time of prescription refills.

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

As of December 31, 2021, we had approximately $5.3 million of inventory. Our inventory significantly exceeds forecasted demand for 2022, therefore, $3.9 million of inventory has been classified as long-term on our balance sheet as of December 31, 2021. This amount of inventory creates a risk of an adverse financial impact from inventory obsolescence.

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.

Patents and Patent Applications

As of February 1, 2022, we held more than 195 patents and patent applications, including 112 issued U.S. patents, 42 U.S. patent applications, and 45 international patents and applications. All of our current issued patents are projected to expire between 2026 and 2034.

We 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."

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, 2022, our trademark portfolio consisted of six US trademark registrations, including electroCore, gammaCore and gammaCore Sapphire, twelve international trademark registrations, and seven pending US and international trademark applications.

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

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

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

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

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

We believe that our products are or would be classified as either Class I or Class II devices.

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. We do not believe our products are or would be classified as Class III devices.

510(k) Clearance

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

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

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

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

EUA Approval

The Commissioner of the FDA, under delegated authority from the Secretary of the U.S. Department of Health and Human Services, or DHHS, may, under certain circumstances, issue an EUA that would permit the use of an unapproved drug product or unapproved use of an approved drug product.

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 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.

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

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;
- notices of corrections or removals; and
- HIPAA compliance around patient information.

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;
- criminal prosecution; or
- reputational damage.

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

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.

In 2014, we received CE Certificate of Conformity in the European Economic Area, or EEA, for our gammaCore therapy to treat, primary headache, including migraine, CH, and hemicrania continua, as well as medication overuse headache in adults. The CE Certificate of Conformity was extended to additional indications, including for the treatment or prevention of symptoms of reactive airway disease, which includes asthma, bronchoconstriction, exercise induced bronchospasm, and COPD in adults.

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

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

Moreover, in May 2017, the EU Medical Devices Regulation 2017/745, or MDR was adopted. The MDR repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA Member State laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The MDR will be applicable on May 26, 2021. Once applicable, the new regulations will among other things:

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

It was necessary for notified bodies to be accredited by the EU Member States' accreditation bodies to conduct assessment procedures for medical devices in accordance with the Regulation. We have the necessary certificates for the MDR.

On March 29, 2017 the United Kingdom formally notified the EU of its intention to withdraw from the Union pursuant to Article 50 of the Lisbon Treaty, commonly referred to as Brexit. The United Kingdom and EU have agreed on the terms of the exit deal, which included a transitional period following the United Kingdom's exit which occurred on January 31, 2020. The transitional period ended on December 31, 2020. The effects of Brexit will be determined by the EU–UK Trade and Cooperation Agreement which was agreed on December 24, 2020 and ratified by the UK Parliament on December 30, 2020 and was "provisionally" applied by the EU from December 31, 2020. Following Brexit, EU law and the EU Court of Justice no longer have supremacy over British laws or its Supreme Court. The United Kingdom's European Union (Withdrawal) Act 2018 retains relevant EU law as domestic law, which can be amended or repealed. The United Kingdom's withdrawal from the EU could lead to legal uncertainty and potentially divergent national laws and regulations in the EU and the United Kingdom. Given the lack of comparable precedent, it is unclear what Brexit's financial, regulatory, and legal implications will be and how it will affect us. However, potentially changing regulatory schemes and tariffs engendered by Brexit may add additional complexity, cost and delays to the operations of electroCore UK Ltd., and in marketing or selling our products in both the United Kingdom and the EEA. Our revenue and profit, supply and demand for our products, and customer retention and acquisition in both the long term and short term could be adversely affected. CE Certificates of Conformity issued by a notified body accredited in the EU may no longer be recognized in the United Kingdom. Similarly, notified bodies accredited in the United Kingdom will no longer be able to issue CE Certificates of Conformity. Obtaining new CE Certificates of Conformity or certification for the United Kingdom may have a significant impact on our activities. Finally, Brexit may also disrupt the way that the United Kingdom interprets obligations under CE Certificates of Conformity.

Other Regulations

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

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

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

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

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

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

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

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

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

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

Data Protection Legislation: We are subject to laws and regulations in non-US countries covering data privacy and the protection of health-related and other personal information. The EU, EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. The EU General Data Protection Regulation, or GDPR, became applicable on May 25, 2018, and is directly applicable in each EU member state and may result in a more uniform application of data privacy laws across the EU. The GDPR imposes strict requirements and onerous accountability obligations on companies that process personal data, especially if they process sensitive personal data (such as data concerning health), including significant fines for non-compliance with the GDPR. Implementation of the GDPR has influenced other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 27, 2019, California adopted the California Consumer Privacy Act of 2019, or CCPA. The CCPA has been characterized as the first "GDPR-like" institutes a comprehensive consumer privacy framework. The CCPA became effective January 1, 2021. Like the GDPR, the CCPA imposes strict requirements and obligations on companies that collect, use, and share personal information. Fines and penalties for non-compliance can be substantial. Unlike the GDPR, the CCPA gives California residents a private right of action where California resident's nonencrypted and nonredacted personal information is subject to a date breach as a result of a business's failure to implement reasonable security procedures. In November 2020, California voters passed Proposition 24, also known as the California Privacy Rights Act, which amends and expands the CCPA, effective January 1, 2023.

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

Healthcare Reform

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

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

Federal Contracting Regulations

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

Human Capital Resources

As of March 1, 2022, we employed 52 full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

We believe our success depends on our ability to attract, develop and retain key personnel. The skills, experience and industry knowledge of key employees significantly benefit our operations and performance. Our board of directors and management oversee various employee initiatives.

Employee health and safety in the workplace is one of our core values. The COVID-19 pandemic has underscored for us the importance of keeping our employees safe and healthy. In response to the pandemic, the Company has taken actions aligned with best practices so our employees can continue to safely and effectively perform their work.

Company History

electroCore, Inc. was founded in 2005 as a limited liability company, which converted into a Delaware corporation pursuant to a statutory conversion effective June 21, 2018. The Company is headquartered in New Jersey, and has two wholly owned subsidiaries: electroCore Germany GmbH, and electroCore UK Ltd. The Company has ceased its operations in Germany, although sales to Germany are still supported by electroCore UK Ltd. In addition, an affiliate, electroCore (Aust) Pty Limited, or electroCore Australia, was subject to electroCore's control on a basis other than voting interests and is a variable interest entity, or VIE, for which electroCore was the primary beneficiary. This VIE has been inactive since May 2017 and was terminated in 2021.

Our Internet website address is www.electrocore.com. The content reflected on our website is not incorporated by reference herein unless expressly noted.

Available Information

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

Item 1A. Risk Factors.

RISK FACTORS

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

Risks Related to COVID-19

The coronavirus pandemic could have a significant negative impact on our business, revenues, financial condition and results of operations.

The persistence of the coronavirus pandemic has severely depressed the level of economic activity around the world. Many businesses and governments have taken preventative or protective actions, including restrictions on travel and business operations, and advising or requiring individuals to limit or forego their time outside of their homes. Temporary closures of many businesses have been ordered and numerous other businesses have temporarily closed voluntarily. Further, individuals' ability to travel has been curtailed through mandated travel restrictions, voluntary or mandated closures of travel-related businesses, as well as quarantines, shelter-in-place/stay-at-home and social distancing orders.

This coronavirus pandemic has also impacted, and may continue to impact, our headquarters, manufacturing, and warehousing and distribution facilities, as well as those of our third-party vendors, including through the effects of facility closures, employee furloughs, reductions in operating hours, staggered shifts and other social distancing efforts, labor shortages, decreased productivity and unavailability of materials or components. For example, we have limited access to our New Jersey office as a result of state-imposed restrictions. Furthermore, the recent Biden administration's executive order requiring all on-site and remote federal employees, contractors and sub-contractors to be vaccinated against COVID-19 or receive an approved medical or religious exemption by December 8, 2021 may apply to us because of our Federal Supply Schedule Medical Equipment and Supply contract. Failure to comply with the executive order could lead to loss of the contract, which could have a material adverse effect on our business, revenues, financial condition and result of operations. In light of the executive order, we implemented a mandatory COVID-19 vaccination policy for all employees. There are, however, ongoing challenges in the federal courts regarding the validity of the executive order, which could lead to future changes to our own policies depending on the outcome of those cases. All of our U.S. employees have to provide proof of vaccination subject to medical and religious exemptions. To the extent an employee qualifies for a medical or religious exemption, we will collaborate with the exempt employee to explore reasonable accommodation options that may permit the employee to perform the essential functions of their job without being vaccinated. We will be unable to accommodate an employee's exemption request if such accommodation would prevent an employee from performing the essential functions of their job, or would result in undue hardship, which includes, but not limited to, a risk of harm to others. There can be no assurance that this policy or any future policies whether adopted in order to comply with applicable rules and regulations or otherwise will not have an adverse effect on our recruitment and retention of, and relations with our employees. The coronavirus pandemic may also impact our ability to sell our product, ship our product on a timely basis and may increase our costs.

The spread of coronavirus has also caused us to modify our business practices (including social distancing practices, requiring non-essential production related team members to work remotely where possible, restricting business travel, cancelling certain events, and limiting visitor access to our facilities), and we may take further actions as may be required by government authorities or that we determine are necessary or advisable. Work-from-home and other measures introduce additional operational risks, including cybersecurity risks, and have affected the way we conduct our business, which could have an adverse effect on our operations. There is no certainty that such measures will be sufficient to mitigate the risks posed by the virus, and illness and workforce disruptions could lead to unavailability of key personnel and harm our ability to perform critical functions. In addition, work-from-home and related business practice modifications present significant challenges to maintaining our corporate culture, including employee engagement and productivity, both during the immediate pandemic crisis and as we make additional adjustments in the eventual transition from it. Implementing new business practices in order to protect employees, vendors and other parties with whom we interact may result in increased costs. Furthermore, even if we follow what we believe to be best practices, there can be no assurance that our measures will prevent the transmission of COVID-19 between employees. Any incidents of actual or perceived transmission may expose us to liability claims, adversely impact employee productivity and morale, and result in negative publicity and reputational harm.

Additionally, our sales and marketing efforts are, and may from time to time be, adversely affected by protocols for screening and restricting outside visitors and vendors that have been adopted by the Department of Veterans Affairs, commercial prescribers and other third parties. Officially imposed quarantines and self-quarantines could also interfere with patients' ability to see a health care provider and obtain our gammaCore therapy.

The degree to which coronavirus impacts our results will continue to depend on future developments that are highly uncertain and cannot be predicted, including, without limitation, the timing, extent, trajectory and duration of the pandemic, the development, rollout and availability of effective treatments and vaccines, the imposition of protective public safety measures, vaccine mandates, the transmissibility and effects of new coronavirus variants such as those experienced with respect to the Omicron variant beginning in early December 2021, and how quickly and to what extent normal economic and operating conditions can resume, if at all. These uncertainties may result in delays or modifications to our plans, initiatives and results.

For the reasons set forth above and other reasons that may come to light due to the coronavirus outbreak and any associated protective or preventative measures, we are unable to reasonably estimate coronavirus' impact to our business, revenues, financial condition and results of operations. We are similarly unable to predict the degree to which the pandemic impacts our customers, suppliers, vendors, capital markets, and other partners, and their financial conditions, but a material effect on these parties could also adversely affect us.

The impact of coronavirus could also exacerbate other risks discussed below, which could in turn have a material adverse effect on us. Developments related to coronavirus have been rapidly changing, and additional impacts and risks may arise that we are not aware of or able to appropriately respond to currently.

More generally, in the future, our business, financial results, and financial condition may be negatively impacted by the effects of other disease outbreaks, epidemics, pandemics, or similar widespread public health concerns.

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

We recently launched new cash pay initiatives, including our gConcierge and gCDirect programs, and patients and providers may be slow to adopt these programs or their pricing which could adversely impact our business and financial results.

We currently have a small cash-pay business channel, which includes the recently launched e-commerce websites for our gConcierge and gCDirect programs, and intend to expand our direct-to-consumer business channel by increasing our advertising and promotional activities in 2022. This will require significant investment and expansion of our sales and marketing capabilities and further development by us and third parties of telehealth features relating to this business channel. We have limited experience with scaling and commercializing a direct-to-consumer cash-pay business channel in the United States and abroad, which may impact our ability to rely on this channel as a positive source of revenue. If we are unsuccessful in executing our commercialization efforts in this business channel and do not achieve the sales levels that we expect, we will be unable to recover these investments. Additionally, there is a risk that potentially lower pricing of our therapy in the direct-to-consumer cash-pay business channel could lead to lower pricing and reimbursement in our legacy business channels and, therefore, have an adverse impact on our financial position and results of operations, and heighten our need to obtain additional capital to support our business.

If third-party payers do not provide adequate coverage and reimbursement for the use of gammaCore, it may affect our ability to generate significant revenues.

Some of our success in marketing and commercializing gammaCore depends and will continue to depend 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. Moreover, if we cannot obtain adequate coverage for and reimbursement of the cost of our products, we cannot provide assurance that patients will be willing to incur the full cost of our gammaCore therapy. In the United States, we expect to derive nearly all of our sales from prescriptions of gammaCore written by physicians. Access to adequate coverage and reimbursement by third-party payers for our gammaCore therapy or the willingness of patients to bear the entire cost of our therapy is essential in the acceptance of our products by physician, patients and other customers for our therapy.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for our gammaCore therapy exists among third-party payers. Therefore, coverage and reimbursement for our gammaCore therapy can differ significantly from payer to payer. In addition, payers continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our gammaCore therapy to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as 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 or if reimbursement rates change, in either the United States or internationally, the demand for our product and our revenues will be adversely affected.

We have a limited history commercializing our gammaCore therapy through direct-to-consumer channels and commercial success is uncertain.

As a small company with a limited history of selling our gammaCore therapy and which has primarily focused on physician adoption and commercial payer and government sales channel to date, we have limited experience engaging in direct-to-consumer commercial activities and limited established relationships with marketing agencies, analytic platforms, and social media following, all of which is becoming increasingly important to direct-to-consumer initiatives. We may be unable to gain broader market acceptance in direct-to-consumer channels of gammaCore therapy in the United States or abroad for a number of reasons, including:

- established competitors with strong relationships with customers, including ecommerce and telehealth platforms, systems, marketing agencies and a critical mass of existing patients;
- 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 marketing team and the learning curve required to gain experience selling our product direct-to-consumer;
- 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.

Any significant disruption to our e-commerce business could result in lost sales.

We recently launched new cash pay initiatives for our gammaCore therapy, including our e-commerce websites in both the United States and United Kingdom. Online sales are subject to a number of risks. System interruptions or delays could cause potential patients to fail to purchase our products and could harm our brand. The operation of our direct-to-consumer ecommerce business depends on our ability to maintain the efficient and uninterrupted operation of online prescription generation, order-taking and fulfillment operations. Our ecommerce operations subject us to certain risks that could have an adverse effect on our operating results, including risks related to the computer systems that operate our website and related support systems, such as system failures, viruses, denial of service attacks, computer hackers, data privacy breaches and other disruptions. If we are unable to continually add software and hardware, effectively upgrade our systems and network infrastructure and take other steps to improve the efficiency of our systems, system interruptions or delays could occur that would adversely affect our operating results.

We utilize third-party vendors for our customer-facing ecommerce technology, portions of our prescription generation, order management system, and fulfillment internationally. We depend on our technology vendors to manage "up-time" of the front-end ecommerce store, manage regulatory control measures around prescriptions, the intake of our orders, and export orders for fulfillment. Any failure on the part of our third-party ecommerce vendors or in our ability to transition third-party services effectively could result in lost sales and harm our business.

We are subject to increasing operating costs and inflation risks which may adversely affect our performance.

While we may attempt to offset potential increases in operating costs through a variety of measures focused on increasing revenues or reducing operating expenses, there is no assurance that we will be able to do so. Therefore, operating costs may rise faster than associated revenues resulting in a material negative impact on our cash flow and margins.

We are also impacted by inflationary increases in wages and benefits whether driven by competition for talent or ordinary course pay increases, as well as other rising costs. Increases in the rate of inflation could also significantly impact our cost base. In all countries in which we operate, wage inflation, whether driven by competition for talent or ordinary course pay increases, may also increase the cost of our cost products and reduce our profitability if we are not able to pass those costs on to our patients and consumers or charge premium prices when justified by market demand.

We have a history of significant losses. If we do not achieve and sustain profitability and positive cash flow from operations, 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, fund our research and development activities, and obtain regulatory clearance or approval for other products or indications in the United States and internationally. We have never been profitable and have incurred net losses in each year since our inception.

We incurred net losses of $17.2 million and $23.5 million for the year ended December 31, 2021 and 2020, respectively. As of December 31, 2021, our accumulated deficit was $124.2 million. Our prior losses, combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders’ deficit and working capital.

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

Even if we are able to increase sales of gammaCore, increase adoption of gammaCore therapy among physicians, payers, patients, and consumers and achieve desired payer coverage and reimbursement levels and increased consumer demand, we may not achieve profitability and even if we do, we may not be able to sustain or increase profitability in subsequent periods. If we fail to become profitable or are unable to sustain profitability, then we may be unable to continue our operations at planned levels and be forced to further reduce or terminate our operations. As of December 31, 2021, we had cash and cash equivalents and marketable securities of $34.7 million. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and ultimately, potentially cease operations. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development, and marketing 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.

Our plans to expand our direct-to-consumer cash-pay business channel may not be able to generate significant revenues.

We currently have a small direct-to-consumer cash-pay business channel, which we are planning to expand in 2022 and beyond. This will require significant investment in and expansion of our sales and marketing capabilities and use of third-party telehealth providers or development of our own telehealth platform. If we are unsuccessful in executing our commercialization efforts in this business channel and do not achieve the sales levels that we expect, we may be unable to recover these investments. Additionally, there is a risk that expanding our direct-to-consumer cash-pay business channel could depress pricing with third-party payers and, therefore, have an adverse impact on our results of operations.

We must successfully attract, hire, train and retain qualified professionals to service our direct-to-consumer sales channels and we must productively deploy our professionals to become profitable.

Identifying, recruiting, hiring and retaining professionals, including employees, independent contractors and consultants with diverse skill sets across our broad geography of operations, and consistent with servicing our existing, new and evolving sales channels, direct-to-consumer is critical to our sales strategy. The market for qualified professionals is evolving, dynamic and increasingly challenging. Our corporate reputation is a significant factor consumers' evaluation of whether to buy our products or potential employees' evaluation of whether to join our company. If we are unable to recruit skilled professionals and if we do not deploy those professionals productively, our results of operations may be adversely impacted. We must manage our sales and marketing team well and plan and train for future needs effectively while accurately predicting physician, patient, and consumer demand. We may not be able to retain such talented professionals long-term for a variety of reasons including their desire to remain as independent content creators rather than full-time employees. If we are unable to attract, hire, train and retain highly skilled professionals and productively deploy them on our sales and marketing efforts, we will jeopardize our ability to develop ongoing and future sales, which could adversely affect our financial condition and results of operations.

Competition for highly skilled professionals is intense in the markets where we operate, and we may experience significant employee turnover rates due to such competition. If we are unable to retain professionals with specialized skills, our revenues, operating efficiency and profitability will decrease. Cost reductions, such as reducing headcount, or voluntary departures that result from our failure to retain the professionals we hire, could negatively affect our reputation as an employer and our ability to hire skilled professionals to meet our business requirements. Increased compensation to retain skilled professionals could lead to lower margins or to higher costs and price increases that may in turn lead to a decline in demand for our products.

Any significant growth in the market for our products and services or our entry into a new market may require an expansion of our employee base for managerial, marketing, operational, financial and other purposes. During any period of growth, we may face problems related to our operational and financial systems and controls, including quality control and delivery and service capacities. We would also need to continue to expand, train and manage our employee base. Continued future growth will impose significant added responsibilities upon the members of management to identify, recruit, maintain, integrate and motivate new employees.

If we experience price fluctuations for our products and we are unable to reduce our expenses, including the per unit cost of producing our products, there may be a material adverse effect on our business, results of operations, financial condition and cash flows.

We anticipate that we will experience, price fluctuations for our products due to pricing pressure relating to our efforts to drive consumer demand. We may also face pricing pressure from managed care organizations and other third-party payors due to increased market power of our payors as the medical device industry consolidates, and increased competition among suppliers, including manufacturing services providers. If the prices for our products decrease and we are unable to reduce our expenses, including the cost of sourcing materials, logistics and the cost to manufacture our products, our sales, results of operations, financial condition and cash flows will be adversely affected. The global COVID-19 pandemic may result in increased costs for manufacturing and outsourced services while also causing additional pressure to reduce the prices for our products if a recession or depression occurs and people are unable to afford our products. We cannot predict the ultimate impact that the COVID-19 pandemic and its effects could have on our business operations, financial condition and cash flows. Any increased or unexpected pricing pressures, costs, delays or failures to achieve cost savings, or unexpected risks we encounter in our business, including those caused by factors outside our control, could adversely affect our business, results of operations, financial condition and cash flows.

Future acquisitions, strategic investments or alliances could disrupt our business and harm our business, financial condition and operating results.

We may in the future explore potential acquisitions of companies or technologies, strategic investments, or alliances to strengthen our business. Acquisitions involve numerous risks, any of which could harm our business, including:

- regulatory hurdles;
- anticipated benefits may not materialize;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- integration of the acquired company's products and technology;
- integration of the acquired company's accounting, management information, human resources and other administrative systems;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked effective controls, procedures and policies;
- coordination of product development and sales and marketing functions;
- liability for activities of the acquired company before the acquisition, including relating to privacy and data security, patent and trademark infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, users, former stockholders or third parties.

Failure to appropriately mitigate these risks or other issues related to such acquisitions and strategic investments could result in reducing or completely eliminating any anticipated benefits of transactions, and harm our business generally. Future acquisitions could also result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, amortization expenses or the impairment of goodwill, any of which could harm our business, financial condition and operating results.

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 for at least the next 12 months from the date the financial statements included in this Annual Report are made available as we continue seeking to invest in our business. We believe that our growth will depend, in part, on our ability to fund our commercial efforts for our gammaCore therapy, and to opportunistically pursue research and development activities for additional indications for our gammaCore therapy. Our existing resources are unlikely to allow us to conduct all of the activities that we believe could be beneficial for our future growth. As a result, we will need to seek additional funds in the future or curtail or forgo some or all of such activities. If we seek to and are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. Although we expect that our existing capital resources and cash flow, will enable us to fund the operating expenses and capital expenditure requirements of our current operating plan for at least the next 12 months from the date the financial statements included in the Annual Report are made available, this estimate is based on assumptions that may prove to be wrong, and we could exhaust or significantly diminish our available capital resources sooner than we expect. Changes, including those relating to the payer and competitive landscape, our commercialization strategy, our development activities and regulatory matters, may occur beyond our control that would cause us to consume our available capital more quickly. Our future capital requirements will depend on many factors, including:

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

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

Our lack of sufficient liquidity could make it more difficult for us to secure additional financing terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our stock price generally. Our ability to continue our operations depends upon, among other things, our ability to increase revenue, reduce operating expenses and obtain additional funding through the sale of equity and or debt securities, debt financing, a strategic transaction or otherwise. However, there are significant risks and uncertainties as to our ability to achieve these goals or obtain required funding on commercially reasonable terms or at all, including as a result of the adverse impact on our business from the COVID-19 pandemic. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and ultimately, potentially cease operations.

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

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.

Changes in certain areas of our business have resulted in the adoption of new accounting principles.

Our evolving commercial strategy has resulted in the launch of cash pay models which under GAAP will lead to the cost of our goods being treated as licensed products pursuant to which the licensed starter kit will be classified as an "other asset" on the company's balance sheet and the cost of the starter kit will be recognized over the license period based on the estimated useful life of the kit, while the cost of goods sold related to the therapy will be expensed upon shipment. This change results in a different accounting methodology which may affect the value of assets on our balance sheet. The new accounting practices could cause our results of operations to have greater variability due to the impact of changes on the estimated recoverability of such asset values.

In addition, licensed product accounting is based off a series of useful life assumptions that may prove to be inaccurate and will be subject to change from time to time, all of which can result in fluctuations from period to period for balance sheet items and have a related impact on our results of operations.

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

We received an EUA from the FDA in July 2020 to facilitate the study and clinical use of gammaCore Sapphire CV for the acute treatment of asthma exacerbations in known or suspected COVID-19 patients. However, there can be no assurance as to the impact, if any, that the EUA and commercialization of gammaCore Sapphire CV will have on us, our business, operations or financial condition.

On April 2, 2020, we announced the submission of an EUA application to the FDA to facilitate the study and clinical use of gammaCore Sapphire CV for the acute treatment of asthma exacerbations in known or suspected COVID-19 patients. On July 13, 2020, we announced that the FDA had granted the EUA.

Unless earlier terminated or revoked by the FDA, the EUA is expected to remain in effect for the duration of the COVID-19 pandemic justifying emergency use. The termination, revocation or expiration of the EUA could have a material adverse effect on the sales of gammaCore and the results of our operations and financial condition. In addition, if the EUA terminates, is revoked or expires, we will be obligated to seek return of the devices from physicians and patients, which could be expensive and time-consuming. Additionally, we may have to incur targeted marketing and other expenditures to achieve sales of the gammaCore Sapphire CV.

We have limited experience with commercializing a respiratory product in the United States. We did not recognize material revenue from sales of our gammaCore Sapphire CV during the fiscal year ended December 31, 2021. We may be unable to successfully commercialize or gain market acceptance of gammaCore Sapphire CV and may not be able to obtain adequate coverage and reimbursement for gammaCore Sapphire CV from third-party payers.

As a result of these and other significant challenges and uncertainties, there can be no assurance as to what impact, if any, the EUA will have on us, our business, operations or financial condition.

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

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

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

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. In addition, possible sales in our EUA business channel to hospitals, which may involve higher credit risks than sales to other payers.

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

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

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

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

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

We must demonstrate to patients, physicians and third-party payers the medical and economic benefits of our gammaCore therapy compared to those of our competitors or other available therapies and such comparisons may not be realizable.

Physicians play a significant role in determining the course of a patient's treatment and, as a result, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing our gammaCore therapy to physicians. We have received several 510(k) clearances from the FDA for gammaCore therapy, however, such clearances do not necessitate adoption by physicians. In order for our gammaCore therapy to gain widespread adoption, we must successfully demonstrate to physicians the medical and economic benefits of our gammaCore therapy compared to competitors' products, including (i) BOTOX marketed by Allergan plc, (ii) CGRP receptor agonists marketed by Amgen Inc. (with a co-marketing arrangement with Novartis International AG), Allergan plc, Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Biohaven Pharmaceuticals Inc., (iii) lasmiditan, marketed by Eli Lilly, (iv) Vycpti, an intravenous preventive treatment for migraine marketed by H. Lundbeck A/S, and (v) neuromodulation devices that have been marketed for the acute treatment and/or prevention of migraine, including the Cefaly and Nerivio devices. We also may face challenges because noninvasive VNS, or nVNS, is relatively new as compared to existing traditional treatments for cluster and migraine headaches. Furthermore, the competitive landscape for COVID-19 therapies is crowded and continues to evolve at a rapid pace. Various other companies, many with greater resources, are developing or commercializing treatments that potentially compete with gammaCore Sapphire CV. This competition could have a material adverse effect on potential acceptance, use, pricing and sales of gammaCore Sapphire CV.

Acceptance of our gammaCore therapy depends on educating patients and 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 patients and physicians of the merits of our gammaCore therapy or educating them on the benefits of our gammaCore therapy, they may not seek a prescription or 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, patients and physicians may not use it. In such circumstances, our results of operations would be materially adversely affected.

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

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

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

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

Our operating results may vary significantly from quarter to quarter because of seasonality, bulk orders, shipments to distributors 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;
- patients' acceptance of gammaCore therapy;
- payor adoption;
- estimated useful life of products
- the timing of when individual payer coverage becomes available;
- patient and physician product returns;
- the timing, expense and results of research and development activities, future clinical trials and regulatory clearance or approvals;
- fluctuations in our expenses associated with expanding our commercial operations and operating as a public company;
- fluctuations in our marketing spend to drive patient purchases;
- the introduction of new products, therapies and technologies by competitors;
- the productivity of our field sales function;
- supplier, manufacturing or quality problems with our products;
- the timing of stocking orders from our distributors;
- changes in our pricing policies or in the pricing policies of our competitors or suppliers;
- adverse developments in coverage amounts, benefit pathway, or government and third-party payers' reimbursement policies; and
- the timing of customer budget cycles.

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

We derive a material portion of our revenue from a limited number of customers, and the loss of one or more of these customers could adversely impact our business, results of operations, and financial condition.

Our customer base is concentrated. During the years ended December 31, 2021 and 2020, revenue from VA/DoD facilities pursuant to our qualifying contract under the Federal Supply Schedule and open market sales represented 60% and 58% of our total revenue, respectively. In 2021, four specific VA/DoD facilities represented approximately 51% of our revenue from this channel, and two of those facilities each accounted for more than 10% individually. If we were to lose one or more of our significant customers, our revenue may significantly decline. The loss of one or more of our significant customers could adversely affect our business, results of operations, and financial condition.

In addition, our direct-to-consumer enablement platform is backed by a dispense who acts as a stocking distributor. If the direct-to-consumer initiatives are successful, there may create a new concentrated customer. Any issues that arise with respect to our direct-to-consumer enablement platform supplier could adversely affect our business, results of operations, and financial condition.

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, customer service, 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.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could harm our business.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base.

Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, distributors and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of the acquired business; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms or at all or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock or other equity-linked securities as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our stock as consideration.

If serious adverse events or other undesirable side effects are identified during the use of our gammaCore therapy in clinical trials or IITs (collectively and unless the context requires otherwise, "clinical 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 future clinical trials, or could make it more difficult for us to enroll patients in 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.

Commercialization of our gammaCore Sapphire therapy for additional neurological conditions may require clinical trials, which are very expensive, take a long time to complete, and are 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, clinical trials or commercial success.

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

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

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

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

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

If we are unable to enroll patients in future clinical trials, our research and development efforts could be adversely affected.

Identifying and qualifying patients to participate in future clinical trials for our gammaCore therapy in additional areas of indications is critical to our success. Successful and timely completion of future 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 future 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 clinical trials altogether.

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

- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size of the patient population required for analysis of the trial's primary endpoints;
- competition for patients for competitive product candidates undergoing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the design of the trial;
- the patient referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion;
- the ability to obtain and maintain patient consents;
- the number of patients with the indication being studied and the difficult of diagnosing the relevant condition or disease; and
- the proximity and availability of clinical trial sites for prospective patients.

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

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

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

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

- the FDA or other regulators disagreeing as to the design, protocol or implementation of 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, due to COVID-19 or other factors, and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality of the product candidate falling below acceptable standards;
- the inability to manufacture sufficient quantities of our gammaCore therapy to commence or complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

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

We could also encounter delays if a clinical trial is suspended, terminated, or paused by us, as we have done with our PREMIUM II trial, by the IRBs or ethics committees of the institutions at which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

If we experience delays in the commencement or completion of any clinical trial of our product candidates, or if any of our future 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 clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence sales and generate associated revenue. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial, suspension or revocation of expanded regulatory clearance or approval of our product candidates. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

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

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

We have previously implemented reductions in force affecting a large portion of our workforce, redeployed resources across our organization and taken other measures to reduce our operating expenses. These efforts do not assure profitability. Furthermore, no assurance can be given as to the need to implement additional cost reductions in the future. Cost savings may also be offset by future hiring or other costs incurred in pursuing strategic objectives. Reductions in force, strategic redeployment and other cost-cutting measures could adversely affect morale in our organization and our reputation as an employer, which could lead to the loss of valued employees and could make it more difficult for us to hire new employees in the future, and the reduction of our headcount could adversely affect our operations and make it more difficult for us to pursue new opportunities and initiatives in the future.

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

We have a relatively short history of operating as a commercial company. We intend to seek to continue to grow our existing headache business and our COVID-19 business pursuant to the EUA, 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 sales force in the United States requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our commercialization and development goals.

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

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

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

If we fail to develop and retain an effective sales force, our business could suffer.

In order to continue to market and sell our gammaCore therapy, we may in the future need to substantially expand our direct sales force. There is significant competition for such personnel. Once hired, the training process is lengthy because it requires significant education for new territory business managers to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our territory business managers typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory or VA or DoD facility. 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 have no history of commercializing respiratory products within the United States or selling our gammaCore therapy pursuant to an Emergency Use Authorization. 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 commercialize gammaCore Sapphire CV for the acute treatment of asthma exacerbations in known or suspected COVID-19 patients for a number of reasons, including:

- lack of strong relationships with customers, including physicians, hospitals and third-party suppliers;
- changes to safety labeling for use of gammaCore Sapphire CV pursuant to the EUA
- 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.

We have only a limited history commercializing our gammaCore therapy for the acute treatment of eCH, prevention of cluster headache, preventive and acute treatment of migraine in the United States for which market acceptance and commercial success is uncertain.

As a small company with a limited history of selling our gammaCore therapy, 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, military treatment facilities 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 primary headache treatments that are safer, more effective, less costly, easier to use or otherwise more attractive than our gammaCore therapy, our business and business prospects 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 primary headache markets including those for CH and migraine headache are cost, demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects and sales force 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 US 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 migraine markets.

Many of our current and potential competitors are publicly traded, or are divisions of publicly traded, major pharmaceutical and medical device companies that have substantially greater financial, technical, sales and marketing resources than we do. We will face steep competition from Allergan plc, Amgen Inc., H. Lundbeck A/S, Novartis International AG, Teva Pharmaceutical Industries Ltd., Biohaven Pharmaceuticals Inc. and Eli Lilly and Company, among other established and potential competitors that may be better capitalized and have a history of commercializing products around the world. Also, several neuromodulation devices are approved for the treatment and/or prevention of migraine, including Cefaly, Nerivo or any other neuromodulation devices that may be marketed for use in treating pain associated with primary headache. Cefaly has been granted an OTC clearance allowing it to be sold without a prescription, and the impact of this clearance on the competitive landscape remains to be seen. 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 including any who may compete with us in the direct-to-consumer channel, will take aggressive action to protect their current market position.

We will face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States. In addition, some physicians have a long-standing practice of using the headache products of our larger, more established competitors. Physicians who use our competitors' products for the treatment of 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.

In the United Kingdom, Fremanezumab has been recommended for use in the National Health Service by the National Institute Health and Care Excellence for the treatment of migraine. Although our current business in the United Kingdom is almost entirely for the prevention and treatment of cluster headache, this recommendation may limit our ability to penetrate the migraine market in the United Kingdom.

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

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

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

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

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

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

Sales of gammaCore outside of the United States represents a substantial portion of our net sales. In 2012, commercial operations began in the United Kingdom and Germany and we now sell gammaCore throughout Europe from our UK based subsidiary and via two distribution partners based in Belgium and Lithuania. Outside of Europe we have a network of 8 distribution partners tasked with selling gammaCore to patients in Canada, Australia, New Zealand, United Arab Emirates, Bahrain, Oman, Saudi Arabia, Cyprus, China, Taiwan, Indonesia, Malaysia and Singapore. The sale and shipment of gammaCore across international borders as well as the purchase of components from international sources, subjects us to US and foreign governmental trade 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 Biden may support potential trade proposals (including import tariffs and other tariffs on China), modifications to international trade policy, and other changes that may affect U.S. trade relations with other countries. We source a significant amount of the components used in gammaCore from Chinese sources so any tariffs or other trade restrictions impacting the import of these components from China could have a material adverse impact on us.

In addition, the COVID-19 pandemic has caused many countries to restrict certain manufacturing activities and has severely disrupted the movement of certain goods. As a result, our distributors, agents, and suppliers may not have the materials, capacity, or capability to operate as our business ordinarily requires.

Additionally, 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;
- the imposition of new trade restrictions.; and
- disruptions caused by Brexit

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

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

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

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

We believe that establishing and strengthening the electroCore and gammaCore brands is critical to achieving widespread acceptance of our gammaCore therapy to treat eCH, prevent CH, prevent and treat migraine, and treat acute asthma exacerbations in known or suspected COVID-19 patients and consumers, 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, our direct-to-consumer initiatives, and our ability to provide physicians, patients, and consumers with a reliable product. Given the established nature of our competitors, our lack of commercialization in the United States, and our lack of experience in the direct-to-consumer channels, 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, expand, and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote, expand, and maintain our brand, our gammaCore therapy may not be accepted by physicians and consumers, which would adversely affect our business, results of operations and financial condition.

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

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

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

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

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

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

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

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

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

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

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

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

Effective succession planning is important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving key employees and senior executives could hinder our strategic planning and execution. Our ability to execute our business strategies, ensure a cohesive management team, and attract and retain key executives may be adversely affected by the uncertainty that could be associated with the needing to transition to a new senior leadership.

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, independent contractor influences, other content creators, 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, FTC, and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, such as the General Data Protection Regulation in the European Union, and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

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

The increasing use of social media could give rise to liability.

Social media, including Instagram, Snapchat, TikTok, Facebook and Twitter, is increasingly being used to communicate about our product, clinical development programs, and the conditions our gammaCore therapy is being developed to treat and we are engaging in what we believe is appropriate social media usage in connection with our commercialization efforts for indications for which our therapy has been approved. We intend to do the same for any future indications or products, if approved. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, for our clinical-stage candidates, patients and consumers may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event. When such disclosures occur, there is a risk that study enrollment may be adversely impacted, we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any online platform, including a blog on the Internet, or a post on a website, that can be distributed rapidly and could negatively harm our reputation. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our company policies or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial participants, customers, consumers, and others. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Risk Related to our Dependence on Third Parties

We have relied upon primary, secondary, and sole source third-party suppliers located in China and elsewhere for components and packaging of our gammaCore products, which suppliers have paused delivery at our request, thereby making us vulnerable to supply shortages, price fluctuations, and an inability to reactivate supply chains if necessary, all of 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, disruptions caused by COVID-19, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our ability to supply gammaCore commercially depends, in part, on our ability to obtain a supply of these components that has been manufactured in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We have not entered into manufacturing, supply or quality agreements with suppliers of consumer electronic components, some of which supply components critical to our products. Although we believe that long-term agreements with these suppliers are not necessary as all the components in our products are either high-volume, non-custom commodity components or are readily available from multiple vendors, there can be no assurance that our multiple-source or sole-source suppliers will be able to meet our demand for their products and services, either because of the informal nature of our arrangements with those suppliers, or our limited experience with those suppliers, due to our relative importance as a customer to those suppliers, or due to supply chain disruptions that may arise such as those relating to COVID-19 and the Coronavirus pandemic, the armed conflict between Russia and Ukraine, trade sanctions and similar events. It may be difficult for us to assess the ability of our suppliers 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.

In Europe, we rely on a single third-party distributor to effectively distribute the majority of our products.

We depend in part on a single third-party distributor for the warehousing, programming and shipment of our products in certain territories in Europe. We depend on this distributor's efforts, yet we are unable to control its efforts completely. This distributor typically performs the same services for a variety of other non-competing products that may limit the resources it dedicates to our gammaCore therapy. If our distributor fails 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. In addition, our ability to recruit distributors as well as their effectiveness may be adversely affected by the armed conflict between Ukraine and Russia.

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 distributor, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize our existing distributor effectively, or fail to strike agreements with attractive terms, or if our distributor is not successful in its businesses, our revenue may decrease and our operating results, reputation and business may be harmed.

We rely upon specialty pharmacies to distribute some of our products in the United States.

We depend on specialty pharmacies to distribute our products but are unable to control their performance. These specialty pharmacies 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 these specialty pharmacies will comply with all applicable laws related to the distribution of our products. If they fail to distribute our products in compliance with applicable laws, our operating results and business may suffer. Recruiting, training, and retaining specialty pharmacies in the distribution of our proprietary product offerings requires significant time and resources.

In addition, we previously used a third-party distributor and its affiliate to provide pharmaceutical patient hub services, including patient support and training. This hub was electronically integrated with our proprietary data warehouse system and web portal. Our agreement with this third-party distributor expired in the second quarter of 2020 and we have transitioned to using specialty pharmacies for select services. This may inhibit our ability to gather data directly into our proprietary data warehouse system and web portal, which may result in disruptions in service for patients that are prescribed our therapy and cause them to seek alternative therapy. Specialty pharmacies 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.

We offer health care provider consults for gammaCore Sapphire in the United States and the United Kingdom and rely upon a third-party telehealth platform provider to do so. In the future, we may need to engage other telehealth platform providers for sales of our other products.

We use telehealth providers for gammaCore Sapphire in the United States and the United Kingdom and their performance is not fully within our control. We are unable to ensure that the telehealth providers will comply with applicable laws, and its failure to do so could have an adverse effect on our operating results and business. Additionally, recruiting, training and retaining telehealth platform providers requires significant time and resources. We may need to establish additional relationships with telehealth platform providers for the sales of our other products, but there can be no assurance that we will be able to do so at all or on terms favorable to us.

In the United States we are dependent on a third-party platform to provide patients with an end-to-end experience that would result in a prescription and purchase of gammaCore therapy.

In the United States, we have contracted with Vytal, LLC to provide an end-to-end e-commerce solution that will enable patients to obtain a prescription and purchase gammaCore directly from an online store. The e-commerce and telehealth platform for gammaCore Sapphire and its performance is not fully within our control. We are unable to ensure that the platform will operate consistently or that they will comply with applicable laws, including but not limited to privacy and patient information, and its failure to do so could have an adverse effect on our operating results and business. Additionally, recruiting, training and retaining telehealth module providers requires significant time and resources which may alter the experience of patients in the online store. We may need to establish additional relationships with e-commerce and/or telehealth platform providers for the sales of our other products, but there can be no assurance that we will be able to do so at all or on terms favorable to us.

Vytal, LLC operates its own dispense and will transact as a stocking distributor. We are unable to ensure they will comply with applicable laws and its failure to do so could have an adverse effect on our operating results and business. As a stocking distributor, we are unable to ensure they will have the financial resources to hold adequate inventory levels to support the demand and any shortage of supply may have an impact on our business and financial results.

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

We expect that a majority of our 2022 U.S. sales of gammaCore will be made pursuant to our qualifying contract on the FSS and open market sales to individual VA facilities. Our status as a contractor on FSS means that we are obligated to comply with a variety of federal procurement laws, regulations, and contract terms that require commercial price disclosures, commercial-to-federal price indexing, and compliance with various federal programs. Furthermore, as a federal contractor, we are also subject to contractual remedies and potential administrative, civil, and criminal damages and penalties for noncompliance with contract terms, over billing, or misconduct. Furthermore, the recent Biden administration's executive order requiring all on-site and remote federal employees, contractors and sub-contractors to be vaccinated against COVID-19 or receive an approved medical or religious exemption by December 8, 2021 may apply to us because of our Federal Supply Schedule Medical Equipment and Supply contract. Failure to comply with the executive order could lead to loss of the contract, which could have a material adverse effect on our business, revenues, financial condition and result of operations. In light of the executive order, we implemented a mandatory COVID-19 vaccination policy for all employees subject to religious and medical exemptions. There are, however, ongoing challenges in the federal courts regarding the validity of the executive order, which could lead to future changes to our own policies depending on the outcome of those cases. For now, the cost of maintaining compliance with these requirements could adversely impact us and our business and complying with these requirements could divert managerial and financial resources. Additionally, failure to comply could result in us being excluded from the opportunity to renew existing federal contracts or to bid on federal future contracts for a period of time lasting up to several years. Any of these contingencies could have a material adverse effect on our business, financial condition and results of operations.

Our potential revenue in the United Kingdom is substantially dependent on government funding arrangements and changes in such government policy could cause material harm to our business.

Effective April 1, 2021, gammaCore Sapphire was included in a new long-term reimbursement policy. The MTFM policy, supports the use of NICE-approved, clinically effective and cost-saving medical devices, diagnostics and digital technologies that will improve patient outcomes. In December 2019, NICE published a Medical Technology Guidance document recommending the use of gammaCore for CH within the NHS. In January 2021, gammaCore was recommended for use in treatment of CH in NHS Scotland. This approval was an adoption of the NICE recommendation. Recently, we have announced agreements with new distributors to make gammaCore Sapphire available in several countries beyond the U.S. and United Kingdom. The cost of compliance with applicable UK laws and regulations could negatively harm us and our business. Additionally, the government funding arrangements provided by the NHS and NICE could be withdrawn if we do not comply with the terms and conditions of such arrangements, or if the programs are not extended or curtailed. Any of these contingencies could have an adverse effect on our potential UK revenue.

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

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Currently, we have a number of ongoing IITs. We frequently review both proposals for new trials and the performance of ongoing trials, and our reviews may result in changes to our future obligations. Our reliance on 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 investigator-initiated trials are outside the United States. The performance of these sites may be adversely affected by various issues, including less advanced medical infrastructure, lack of familiarity with conducting clinical trials in accordance with U.S. standards, insufficient training of personnel, communication difficulties or change in local regulations. We remain responsible for ensuring that clinical trials are 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 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.

Additionally, patient enrollment is affected by many factors beyond our control and the control of the third parties upon whom we rely to conduct IITs. As a result, we cannot predict how successful our IITs will be at enrolling patients. In particular, enrollment in our IITs for nVNS stimulation in COVID-19 patients in the United States have been slower than expected.

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

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

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

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

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

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

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

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

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

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

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

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

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

The manufacturing process requires lengthy lead times during which electronic components of our gammaCore therapy may become obsolete, and we may over- or under-estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third-party manufacturers exposes us to greater lead times increasing our risk of adverse financial impact of inventory obsolescence comparatively. In addition, as of December 31, 2021 we had approximately $5.3 million of inventory. Our inventory significantly exceeds current demand for the gammaCore therapy, which also could result in an increased risk of adverse financial impact from inventory obsolescence.

Risks Related to Intellectual Property

Our product development initiatives may be delayed or fail to succeed, and could also lead to challenging intellectual property rights issues.

We may seek to develop new products and technologies, including enhancements of our existing products for nVNS. Developing new products and improving our existing products to meet the needs of current and future patients and consumers requires significant investment in research and development. We do not know whether any such product development activities will result in products that meet necessary standards and performance criteria, whether the development will be completed on a timely basis, or if completed will lead to market acceptance and commercial success. We will need to carefully manage our introduction of any new products. If potential purchasers of new products believe such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have limited experience in managing product transitions. Even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing patient and customer preferences or the introduction by competitors of products embodying new technologies or features. Delays could occur based on a number of issues including the need to investigate third party patents and potential infringement matters, which could impair our development and commercialization efforts.

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 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. There may be prior public disclosures of which we are not aware that could invalidate our patents or a portion of the claims of our patents. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.

- Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications, our ability to obtain patents, or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations.

- Monitoring unauthorized uses of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors' therapies, products and services, and may in the future seek to enforce our patents or other proprietary rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product features, which could reduce demand for our gammaCore therapy. In addition, we may need to defend our patents from third-party challenges, including interferences, derivation proceedings, re-examination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions, or other patent proceedings. We may need to initiate infringement claims or litigation. Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable or may refuse to enjoin the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could place one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have patent portfolios, including significantly broader patent portfolios, to assert against us, if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

- We may not be able to accurately estimate or control our future operating expenses in relation to obtaining, enforcing and/or defending intellectual property, which could lead to cash shortfalls. Our operating expenses may fluctuate significantly in the future as a result of the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our products. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the products or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

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

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

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

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

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

As is the case with other pharmaceutical and medical device companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and medical device industries involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. 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. US 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 for our products 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 the use of our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Regulation of our Industry

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

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

- the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations (Title 21 CFR);
- CE mark requirements of the European Union, or EU, and UKCA mark requirements of the United Kingdom;
- Medical Device Quality Management System Requirements (ISO 13485:2016);

- Occupational Safety and Health Administration requirements;
- Federal Trade Commission;
- health information privacy and security, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and comparable state laws; and
- New Jersey Department of Health Services requirements.

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

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

The advertising, marketing and labeling of medical devices is highly regulated by the FDA and Federal Trade Commission ("FTC"). Our efforts to promote our gammaCore therapy, including via direct-to-consumer marketing or social media initiatives, could subject us to additional scrutiny of our communication of risk information, benefits or claims, by the FDA, FTC, or both.

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

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

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

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

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

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

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

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

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- risk assessment and management;
- marketing, sales and distribution;
- pre-market regulatory clearance and approval;
- conformity assessment procedures;
- record-keeping procedures;
- advertising and promotion;
- recalls and other field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

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

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

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

In the EEA, gammaCore must currently comply with the Essential Requirements laid down in (i) Annex I to Directive 93/42/EEC and (ii) EU Medical Device Regulation 2017/745, or MDR, on the approximation of the laws of the member states relating to medical devices or the EU Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE mark to gammaCore, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure that requires the intervention of a notified body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the notified body would audit and examine the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The notified body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

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

Moreover, in May 2017 the new MDR, entered into force. Following its entry into application in May 2021, the regulation introduced substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the MDR repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The MDR among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. Once applicable, the Medical Devices Regulation will among other things:

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

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

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

The United Kingdom's withdrawal from the EU, or Brexit could lead to legal uncertainty and potentially divergent national laws and regulations in the EU and the United Kingdom. Given the lack of comparable precedent, it is unclear what Brexit's financial, regulatory, and legal implications would be and how it would affect us. However, potentially changing regulatory schemes and tariffs engendered by Brexit may add additional complexity, cost and delays to the operations of electroCore UK Ltd., and in marketing or selling our products in the United Kingdom. Our revenue and profit, supply and demand for our products, and customer retention and acquisition in both the long term and short term could be adversely affected. Since a significant proportion of the regulatory framework in the United Kingdom was derived from EU directives and regulations, the withdrawal of the United Kingdom from the EU could materially impact the regulatory regime with respect to the CE Certificates of Conformity in the United Kingdom. CE Certificates of Conformity issued by a notified body accredited in the EU may no longer be recognized in the United Kingdom. Similarly, notified bodies accredited in the United Kingdom will no longer be able to issue CE Certificates of Conformity. Obtaining new CE Certificates of Conformity or certification for the UK may have a significant impact on our activities. Finally, Brexit may also disrupt the way that the United Kingdom interprets obligations under CE Certificates of Conformity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

gammaCore has been CE Marked in the EEA and cleared by the FDA for the acute treatment of eCH, CH prevention and the preventive and acute treatment of migraine headache in the United States; and gammaCore Sapphire CV has received an EUA from the FDA for the acute treatment of asthma exacerbations in known or suspected COVID-19 patients. We may only promote or market our gammaCore or gammaCore CV therapy for its specifically approved or authorized indications as described on the approved or authorized label. We train our marketing and sales force against promoting our products for uses outside of the approved or authorized 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, approved or authorized by the applicable regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the Stark Law, in the event that third-party payers require us to be a durable medical equipment, or DME, supplier or we sell our products directly to providers who are DME suppliers that submit claims to such payers.

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

- the federal civil False Claims Act, which prohibits, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The federal civil False Claims Act can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. Penalties for a federal civil False Claims Act violation include three times the actual damages sustained by the government, plus significant mandatory civil penalties for each false claim, and the potential for exclusion from participation in federal healthcare programs. There are also federal criminal false claims and federal civil monetary penalty laws that carry significant monetary and other penalties for submissions of false or fraudulent claims and statements;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;

- HIPAA, as amended, and its implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates, relating to the privacy, security and transmission of individually identifiable health information, including mandatory contractual terms as well as privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties, and, in certain circumstances, criminal penalties with fines. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state;

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

- state and foreign law equivalents of each of the above federal laws, such as state anti- kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require device and drug companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device and drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information, such as the CCPA, many of which differ from each other in significant ways and often are not preempted by HIPAA or other federal privacy and security requirements.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with physicians or other entities or individuals in a position to purchase, prescribe or recommend our products. We have entered into consulting agreements and other arrangements with physicians, including some who have ownership interests in us and/or prescribe our products to patients. Compensation under some of these arrangements included the equity interests in our company. We could be adversely affected if regulatory agencies determine our financial relationships with such physicians to be in violation of applicable laws. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

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

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the ACA was signed into law, which included, among other things, comparative effectiveness research initiatives and payment system reforms, including shared savings pilots, and other provisions. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business. Any new limitations on, changes to, or uncertainty with respect to the ability of individuals to enroll in governmental reimbursement programs or other third-party payor insurance plans could impact demand for our product.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. In addition, 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. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 (MACRA), repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

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 products or additional pricing pressures.

Risks Related to Our Common Stock

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock, which could negatively impact the market price and liquidity of our common stock and our ability to access the capital markets.

On December 20, 2021, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we did not meet the minimum bid price of $1.00 per share required for continued listing on The Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1). Pursuant to the initial Nasdaq notice and Rule 5810(c)(3)(A) of the Nasdaq Listing Rules, we have 180 calendar days from the date of the notice, or until June 20, 2022, to regain compliance with the minimum bid price requirement in Rule 5450(a)(1) by achieving a closing bid price for our common stock of at least $1.00 per share over a minimum of 10 consecutive business days.

Such a delisting would have a negative effect on the price of our common stock, impair the ability to sell or purchase our common stock when persons wish to do so, and any delisting could materially adversely affect our ability to raise capital or pursue strategic, financing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Global Select Market could also have other negative results, including the potential loss of institutional investor interest.

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

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

We have broad discretion to determine how to use most of 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 most of our financial resources, including proceeds from financings 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 such financings and such purchase agreement in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

An active, liquid and orderly market for our common stock may not continue to be sustained, 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.

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 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 be sustained 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.

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

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO (December 31, 2023), (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

As a public company, we are required to implement and maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting. Beginning with our second annual report following our IPO, for our fiscal year ended December 31, 2020, management provided a report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we (i) are no longer an "emerging growth company," as defined by the JOBS Act, and (ii) pursuant to new SEC rules, have annual revenues greater than $100 million in the most recent fiscal year for which audited financial statements are available. We do not expect to have our independent registered public accounting firm attest to our management report on internal control over financial reporting for so long as we are an emerging growth company or have annual revenues under $100 million. If we have to design and implement the internal control over financial reporting required to comply with this obligation, such process will be time consuming, costly and complicated.

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66 2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

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

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

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

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

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

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;

- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and

- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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.

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation, or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine, in each case provided that the Chancery Court has subject matter jurisdiction. If the Chancery Court does not have subject matter jurisdiction, then such actions may be brought in any state court located in the state of Delaware, or State Courts, or, if and only if the State Courts lack subject matter jurisdiction, in the federal district court for the District of Delaware.

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

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

The requirements of being a publicly traded company may strain our resources and divert management's attention.

As a publicly traded company, we have incurred, and will continue to incur, significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), as well as rules subsequently implemented by the SEC and Nasdaq, have imposed various requirements on public companies. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These rules and regulations may also make it more difficult and more expensive for us to obtain director and officer liability insurance.

Failure to comply with these public company requirements could subject us to enforcement actions by the SEC, divert management's attention, damage our reputation, and adversely affect our business, results of operations, or financial condition. In particular, if our independent registered public accounting firm is not able to render the attestation report on our internal control over financial reporting in future annual reports on Form 10-K when required under Section 404 of the Sarbanes-Oxley Act, it could result in a loss of investor confidence in the accuracy, reliability, and completeness of our financial reports. We expect that the future loss of our "emerging growth company" status and compliance with these additional internal control and auditor attestation requirements will require management to expend additional time while also condensing the time frame available to comply with SEC reporting requirements, which may further increase our legal and financial compliance costs.

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:

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

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

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 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.

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

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

New legislation or regulation which could affect our tax burden could be enacted by a governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. U.S. federal legislation affecting the tax laws was enacted in December 2017, in the Tax Cuts and Jobs Act; twice in March 2020, first in the Families First Coronavirus Response Act and again in the CARES Act; in December, 2020 in the Consolidated Appropriates Act, 2021; and in March 2021 in the American Rescue Plan Act of 2021. 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. 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 business and stock price could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

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

Item IB. Unresolved Staff Comments

None

Item 2. Properties

Our principal office is approximately 14,000 square feet of office, warehouse and assembly space in Rockaway, New Jersey pursuant to a lease that expires in 2024 (subject to our right to extend for an additional five years). Our former principal office consisted of approximately 25,000 square feet of leased office space in Basking Ridge, New Jersey. Since the spring of 2020, as a result of COVID-19, our employees previously based in Basking Ridge have conducted business remotely as a result of governmental orders and our internal policies designed to protect the health and safety of our employees. In the fourth quarter of 2020, we formally vacated the Basking Ridge, New Jersey facility and the lease to this facility was formally terminated in 2021. Management believes our facilities in Rockaway are currently suitable for their intended use. We may in the future add new facilities or expand or relinquish existing facilities as our needs evolve, and we believe that should the need arise, suitable additional or substitute space will be available as needed to accommodate any expansion of our operations.

Item 3. Legal Proceedings

On July 8, 2019 and August 1, 2019, purported stockholders of our company served putative class action lawsuits in the Superior Court of New Jersey for Somerset County, captioned Paul Kuehl vs. electroCore, Inc., et al., Docket No. SOM-L 000876-19 and Shirley Stone vs. electroCore, Inc., et al., Docket No. SOM-L 001007-19, respectively. In addition to our company, the defendants included present and past directors and officers, Evercore Group L.L.C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for our IPO; and two of our stockholders. On August 15, 2019, the Superior Court entered an order consolidating the Kuehl and Stone actions, which proceeded under Docket No. SOM-L 000876-19. Each plaintiff was appointed a co-lead plaintiff. The plaintiffs filed a consolidated amended complaint, which sought certification of a class of stockholders who purchased our common stock in our IPO or whose purchases are traceable to that offering. The consolidated amended complaint alleged that the defendants violated Sections 11, 12(a)(2) and 15 of the Securities Act with respect to the registration statement and related prospectus for the IPO. The complaint sought unspecified compensatory damages, interest, costs and attorneys' fees. On October 31, 2019, the Company and the other defendants filed a motion to dismiss the complaint or in the alternative to stay the action in favor of the pending federal action (discussed below). On February 21, 2020 the court granted the defendants' motion to dismiss the consolidated amended complaint with prejudice. On March 2, 2020 the court entered an amended order dismissing the consolidated amended complaint with prejudice. On March 27, 2020, the plaintiffs filed a notice of appeal with the N.J. Superior Court - Appellate Division. The appeal was argued on September 27, 2021. On October 8, 2021, the Appellate Division issued an order reversing the decision of the Superior Court. The case was remanded to the Superior Court for oral argument on the motion to dismiss. On November 11, 2021 the defendants filed a supplemental motion to dismiss based on the certificate of incorporation's forum selection clause. On December 10, 2021, the Superior Court heard argument of the original motion to dismiss and the supplemental motion to dismiss based on the federal forum selection clause. On December 14, 2021, the Superior Court granted both motions in their entirety and dismissed the action without leave to re-plead. On January 27, 2022, the plaintiffs filed a notice of appeal to the Appellate Division. A briefing schedule has been set by the Appellate Division for the appeal but an argument date has not been set.

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

In the Turnofsky case, on November 25, 2019, several plaintiffs and their counsel moved to be selected as lead plaintiff and lead plaintiff's counsel. On April 24, 2020, the Court granted the motion of Carole Tibbs and the firm Bragar, Eagel & Squire, P.C. On July 17, 2020 the plaintiffs filed an amended complaint in Turnofsky. In addition to the prior claims, the amended complaint adds an additional director defendant and two investors as defendants, adds a claim against the Company and the underwriters for violating Section 12(a)(2) of the Securities Act. On September 15, 2020, the Company and the other defendants filed a motion to dismiss the amended complaint for failure to state a claim. On November 6, 2020, the plaintiffs filed their opposition to the motion to dismiss. The Company and the other defendants filed reply papers in support of the motion on December 7, 2020. Argument of the motion to dismiss occurred on June 18, 2021. On August 13, 2021, the Court dismissed the amended complaint with leave to re-plead. On October 4, 2021, the plantiffs filed a second amended complaint. On November 17, 2021, the defendants moved to dismiss the new complaint. Briefing on the motion is now complete. Argument of the motion has not yet been scheduled.

The Priewe case was voluntarily dismissed on February 19, 2020.

On March 4, 2021, purported stockholder Richard Martz brought a purported stockholder derivative action in the United States District Court for the District of New Jersey. The action is captioned Richard Maltz, derivatively on behalf of electroCore, Inc., vs. Francis R. Amato, et al., Case 3:21-cv-04135. The defendants include present and past directors and officers of the Company. The plaintiff purports to pursue derivative claims on behalf of the Company in connection with the IPO and actions occurring between the IPO and September 25, 2019. The complaint alleges that demand on the board of directors is excused. The complaint purports to allege claims against the defendants for violating Section 14(a) of the Exchange Act, breaching fiduciary duties, unjust enrichment and waste of corporate assets. The complaint also purports to allege claims for contribution in connection with the Turnofsky case described above, pursuant to Section 11(f) of the Securities Act and Sections 10(b) and 21D of the Exchange Act. The complaint seeks unspecified compensatory damages, interest, costs and attorneys' fees; declaratory relief; and an order requiring changes to corporate governance and internal procedures and a vote on proposed amendments to the Bylaws and Certificate of Incorporation.

On March 8, 2021, purported stockholder Erwin Yuson brought a purported stockholder derivative action in the United States District Court for the District of New Jersey. The action is captioned Erwin Yuson, derivatively on behalf of electroCore, Inc., vs. Francis R. Amato, et al., Case 3:21-cv-04481. The defendants include present and past directors and officers of the Company. The plaintiff purports to pursue derivative claims on behalf of the Company in connection with a 2019 proxy statement and actions occurring from the IPO through September 25, 2019. The complaint alleges that demand on the board of directors is excused. The complaint purports to allege claims against the defendants for violating Section 14(a) of the Exchange Act and breaching fiduciary duties. The complaint seeks unspecified compensatory damages, interest, costs and attorneys' fees; declaratory relief; and an order requiring changes to corporate governance and internal procedures and a vote on proposed amendments to the Bylaws and Certificate of Incorporation.

The plantiffs in the *Maltz* and *Yuson* derivative actions agreed to consolidate and stay those actions. The actions are stayed until and through the resolution of any motion for summary judgment in the *Turnofsky* federal securities class action. A stipulation to that effect was filed by the plaintiffs on April 14, 2021 and ordered by the court on April 30, 2021.

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

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

Stockholders

As of March 1, 2022, there were 373 stockholders of record, which excludes stockholders whose shares are held in nominee or street name by brokers.

Dividend Policy

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

Equity Compensation Plans

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

Issuer Purchases of Equity Securities

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

Use of Proceeds from Registered Securities

Not applicable.

Item 6. Reserved

Not applicable.

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

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

Overview

We are a commercial stage medical device company with a proprietary non-invasive vagus nerve stimulation, or nVNS, therapy, called gammaCore. nVNS is a platform bioelectronic medical therapy that modulates neurotransmitters and immune function through its effects on both the peripheral and central nervous systems. We are initially focused on utilizing gammaCore in the management and treatment of primary headache conditions.

Our gammaCore nVNS therapy is the first non-invasive, hand-held medical therapy applied at the neck as an adjunctive therapy to treat migraine and cluster headache through the utilization of a mild electrical stimulation to the vagus nerve that passes through the skin. Designed as a portable, easy-to-use technology, gammaCore can be self-administered by patients, prophylactically or as needed, without the potential side effects associated with commonly prescribed drugs. When placed on a patient 's neck over the vagus nerve, gammaCore stimulates the nerve's afferent fibers, which may lead to a reduction of pain in patients. gammaCore (nVNS) is FDA cleared in the United States for adjunctive use for the preventive treatment of cluster headache in adult patients, the acute treatment of pain associated with episodic cluster headache in adult patients, the acute and preventive treatment of migraine in adults and adolescent (ages 12 and older) patients, and paroxysmal hemicrania and hemicrania continua in adult patients. gammaCore is CE-marked in the United Kingdom and European Union for the acute and/or prophylactic treatment of primary headache (Migraine, Cluster Headache, Trigeminal Autonomic Cephalalgias and Hemicrania Continua) and Medication Overuse Headache in adults.

Since May 2019, we have primarily focused our sales efforts in two channels, the U.S. Department of Veterans Affairs and U.S. Department of Defense, and the United Kingdom.

More recently, we began making targeted investments to increase the adoption of our gammaCore therapy in both the United States and abroad. We continue to evaluate strategies to expand commercial adoption of gammaCore, including traditional reimbursement models as well as the potential use of e-commerce and cash pay models through direct-to-physician and direct-to-consumer approaches. We expect to make continued targeted investments in the evaluation and possible execution of these strategies in future quarters. We are unable to predict the impact these strategies will have on our financial condition, results of operations and cash flows due to numerous uncertainties.

In addition, we have announced agreements with new distributors to make gammaCore Sapphire available in several countries beyond the U.S. and United Kingdom.

Capital Activities

On January 18, 2022, we filed a Form S-3 registration statement, or the 2022 Shelf Registration Statement, with the SEC, for the issuance of common stock, preferred stock, warrants, rights, debt securities and units, up to an aggregate amount of $75 million. The 2022 Shelf Registration Statement was declared effective on January 25, 2022. The proposed maximum offering price per unit and the proposed maximum aggregate offering price per class of security will be determined from time to time by us in connection with the issuance by us of the securities registered under the 2022 Shelf Registration Statement. Until such time as the aggregate market value of our securities held by non-affiliates equals or exceeds $75 million, the aggregate maximum offering price of all securities issued by the us in any given 12-calendar month period pursuant to this and any of our other registration statements may not exceed one-third of the aggregate market value of our securities held by non-affiliates.

On July 2, 2021, we completed a public offering of 20,700,000 shares of our common stock at a purchase price of $1.00 per share. The net proceeds of the offering to us were approximately $18.8 million, after deducting the underwriting discounts and commissions and other estimated offering expenses. We intend to use the net proceeds of the offering for sales and marketing, working capital, and general corporate purposes. In addition, we believe that opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of, or investments in, complementary companies, medicines, intellectual property, or technologies. While we have no current agreements or commitments for any specific acquisitions, in-licenses or investments at this time, we may use a portion of the net proceeds for these purposes.

On August 30, 2021, we entered into a Securities Purchase Agreement with our legal counsel pursuant to which we issued 952,380 shares of common stock, at a purchase price of $1.05 per share. Upon issuance of the shares, certain of our outstanding financial obligations to our legal counsel were deemed paid and satisfied in full.

On October 4, 2021, we issued 200,000 shares of our common stock in connection with the lease termination related to our former headquarters located in Basking Ridge, NJ.

On March 27, 2020, we and Lincoln Park Capital Fund, LLC ("Lincoln Park") entered into an equity facility purchase agreement ("Purchase Agreement") pursuant to which we had the right to sell to Lincoln Park shares of our common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. In January 2021, we sold 2,750,000 shares of our common stock under the Purchase Agreement, resulting in aggregate proceeds of approximately $6.9 million. On March 11, 2021, we terminated the Purchase Agreement and, accordingly, we will not sell any further shares of our common stock to Lincoln Park under the Purchase Agreement.

Research and Development

Regulatory Clearances

In February 2021, gammaCore received clearance by the FDA for the acute and preventive treatment of migraine in adolescents between 12 and 17 years of age.

In September 2021, we announced the company received Section 510(k) clearance from the United States Food and Drug Administration (FDA) of the company's submission to expand the label of gammaCore nVNS to include the treatment of Paroxysmal Hemicrania (PH) and Hemicrania Continua (HC) in adults.

Outside the US

In August 2011, we received a CE Certificate of Conformity for gammaCore for the treatment of primary headache from the British Standards Institution, a European Union notified body. This CE Certificate of Conformity allowed us to affix the CE Mark on gammaCore and to commercialize it in the European Economic Area and other countries that recognize the European CE Mark. In addition to the CE Certificate of Conformity for primary headache, between September 2011 and October 2013 we received CE Certificates of Conformity on gammaCore covering four other indications for use, including reactive airway disease and gastric motility disorders. In 2019, the National Institute for Health and Care Excellence, or NICE published a Medical Technology Guidance document recommending the use of gammaCore for Cluster Headache or CH within the National Health Service, or NHS, of England and Wales. On January 2021, NHS Scotland adopted the NICE recommendation and recommended gammaCore for use in the treatment of CH in Scotland.

NHS England awarded gammaCore a place on the Innovation Technology Payment, or ITP, program for treatment of patients with reflectory cluster headache, a reimbursement pathway that opened in April 2019. In October 2020, we announced that the ITP program was extended through March 2021. Effective April 1, 2021, gammaCore Sapphire was included in a new long-term, reimbursement policy, titled the MedTech Funding Mandate Policy 2021/22, or MTFM.

In August 2021, we announced the release of an article entitled "gammaCore for Cluster Headaches: A NICE Medical Technologies Guidance" in the journal PharmacoEconomics highlighting the cost impact of gammaCore's non-invasive vagus nerve stimulation therapy platform for patients with cluster headaches. The paper is part of a series that provides insight into the development of NICE medical technologies guidance for new or innovative medical devices or diagnostics. The aim of the guidance is to support the adoption of clinically effective and cost-saving technologies in the UK National Health Service. The paper validated that gammaCore both reduces the frequency and severity of cluster headaches when used with standard of care and provides a £450 per patient savings in the first year of therapy versus standard of care alone.

In October 2021, we announced the publication of a peer-reviewed paper entitled "Non-invasive vagus nerve stimulation for treatment of cluster headache: a retrospective review of prescribing in England," in the British Journal of Healthcare Management. The paper reviews the prescribing trends of gammaCore in England from April 2019 through the end of 2020 and is one of the largest clinical audits of patients with cluster headache. The paper highlights that of the 655 patients who started on gammaCore, 46.3% of patients were prescribed at least one refill and 30.9% were prescribed two or more refills. These real-world results suggest a durable benefit for patients utilizing gammaCore's non-invasive vagus nerve stimulation (nVNS) for cluster headache in England.

In April 2021, we announced that Health Canada has granted regulatory approval for the promotion and sale of the gammaCore Sapphire family of products in Canada for prevention and therapeutic treatment of migraine and cluster headache, as outlined in the registration application with Health Canada. Later in the year, the company received an amended Medical Device License from Health Canada to expand the label of gammaCore nVNS to include the acute and preventive treatment of migraine in adolescents between 12 and 17 years of age. gammaCore is now cleared for most forms of primary headache including the acute and preventive treatment of migraine in adolescents and adults, as well as the acute and preventive treatment of cluster headache in adults.

In December 2021, we announced the launch of an e-commerce shop for patients residing in the United Kingdom. The site, which can be found at www.gammacore.co.uk, requires patients to complete a healthcare questionnaire in order to purchase a gammaCore Sapphire™, non-invasive vagus nerve stimulator (nVNS) device online. The first product launched on the platform is designed to treat menstrual migraine, supporting the 60% of women who report migraine symptoms associated with their menstrual cycle. This platform will allow patients to experience a fully virtual experience by completing an online clinical assessment, having product delivered to their door, and being trained via video calls with a member of the UK customer service team.

Throughout 2021 we continued executing on the plan to expand international distribution by onboarding exclusive distribution partners outside the United States and United Kingdom (Table 1).

Table 1: International Distributor List

Territory	Distributor	Country
North America	RSK Medical	Canada
Eastern Europe	Pro Medical Baltic	Lithuania, Latvia, Belarus, Kazakhstan, and Ukraine
Western Europe	Silvert Medical Nv-Sa.	Belgium, Luxembourg, the Netherlands, and France
Australia	Medistar2 PTY Ltd	Australia
Asia	Kromax International Corp.	Taiwan and China
	Kromax South Asia Pte Ltd.	Malaysia, Singapore, and Indonesia
Middle East	East Agency	Qatar
	Melidonia	Cypress
	Cyrus	United Arab Emirates and Oman
	Medexsol	Saudi Arabia and Bahrain

Impact of COVID-19

We are closely monitoring the impact of the COVID-19 pandemic on all aspects of our business and geographies, including how it will impact business partners, customers and the global supply chain. In particular, the pandemic has resulted in a significant reduction in non-essential contact between patients and healthcare providers, shifting of focus by healthcare providers to the acute treatment of COVID-19 related illness regardless of specialty. We believe these restrictions have limited our sales force's ability to generate additional interest in the Company's products. While we began to experience disruptions from the COVID-19 pandemic during the three months ended March 31, 2020, we are unable to predict the impact that the COVID-19 pandemic may have on our financial condition, results of operations and cash flows due to numerous uncertainties. These uncertainties include the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact, the development, rollout and availability of effective treatments and vaccines, the imposition of various protective public safety measures including vaccine mandates, as well as the transmissibility and effects of new coronavirus variants such as those experienced with respect to the Omicron variant beginning in early December 2021, and the direct and indirect economic effects of the pandemic and containment measures, among others. The outbreak of COVID-19 in many countries, including the United States, has significantly adversely impacted global economic activity and has contributed to significant volatility and negative pressure in financial markets. The global impact of the outbreak has been rapidly evolving and many countries have reacted by instituting quarantines, mandating business and school closures and restricting travel. Certain states and cities, including those where our principal place of business is located and sales force seeks to operate, have also reacted by instituting quarantines, restrictions on travel, "shelter in place" rules, and restrictions on types of business that may continue to operate. We cannot predict if additional states and cities will implement similar restrictions or when restrictions currently in place will expire. As a result, the COVID-19 pandemic is negatively impacting almost every industry directly or indirectly, including industries in which we operate. Further, the impacts of a potential worsening of global economic conditions and the continued disruptions to, and volatility in, the credit and financial markets, consumer spending as well as other unanticipated consequences remain unknown of effective treatments and vaccines.

Because the COVID-19 pandemic affected, among other things, our access to prescribing physicians and their access to headache patients, on March 23, 2020 we suspended our earlier full-year revenue guidance until we could better understand the trajectory of our business, as well as announced a reduction in our activities, and adjusted our cash runway expectations in response to the potential adverse impact caused by the COVID-19 pandemic. Compared to our earlier expectations, we believe that our results for the year ended December 31, 2021 reflect a negative impact from, among other things, the global pandemic. Moreover, our expectations for at least the beginning of 2022 have also been adversely affected by both the uncertainty and potential negative impact of the global pandemic. Depending upon the duration and severity of the pandemic, the continuing effect on our results and outlook over the long term remains uncertain.

In July 2020, the Company received an EUA for use of its gammaCore Sapphire CV nVNS therapy for the acute treatment of asthma exacerbations in known or suspected COVID-19 patients. This EUA is expected to remain in effect for the duration of the COVID-19 pandemic justifying emergency use of these devices unless terminated or revoked by the FDA (after which products may no longer be used). We did not recognize material revenue from the sales of gammaCore Sapphire CV during the year ended December 31, 2021, and we do not expect to recognize material revenue from the sales of gammaCore Sapphire CV in general.

Critical Accounting Policies and Estimates

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

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

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

Revenue Recognition

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

We have a standardized approach to estimate the amount of consideration that we expect to be entitled to, including the impact of discounts and rebates. Our historical collection is an integral part of the estimation process related to revenues and receivables. Further adjustments to the allowances, based on actual receipts, may be recorded upon settlement.

Revenue from the Veterans Administration and the Department of Defense

Revenue from sales of our products is recognized under terms of the Federal Supply Schedule, or FSS, and purchase orders from individual VA sites and a distributor who purchases our products on behalf of the DoD. Revenue from the VA includes sales of therapy for up to 36 months.

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

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

United Kingdom Revenue

In the United Kingdom, an award from the Innovation Technology Payment program of the NHS and evidence-based recommendations published in December 2021 by NICE offer the potential for us to generate revenue from the treatment of CH. This is the primary commercial channel from which our United Kingdom revenue is derived. The first 93 days of therapy is free under this program. The cost to produce the free therapy in the 93-day period is recorded as promotional expense within selling, general and administrative expenses.

Effective April 1, 2021, gammaCore Sapphire will be included in the new MTFM long-term reimbursement policy which supports commissioners and providers in the use of selected NICE approved, clinically effective and cost-saving medical devices, diagnostics and digital technologies that will improve patient outcomes.

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

Recently, product offering in the United Kingdom has expanded to 10-day therapy at a fixed price for menstrual migraine patients purchasing product through our UK e-commerce store. All revenue associated with the menstrual migraine product are paid prior to product being shipped.

United States Commercial Revenue Outside of Federal Supply Schedule Channel

Revenue from our e-commerce and cash pay models through direct-to-physician and direct-to-consumer channel are usually recognized at the time of product shipment or delivery dependent on specific contractual terms, less any discounts or rebates.

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

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

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

Inventories

We value inventory at the lower of cost or net realizable value. Cost is determined on a first in first out basis. This policy requires us to make estimates regarding the net realizable value of our inventory, including an assessment of excess or obsolete inventory. We evaluate inventory for excess quantities and obsolescence based on an estimate of the future demand for our product within a specified timeframe and record an allowance to reduce the carrying value of inventory as determined necessary. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. We evaluate inventory with respect to our operating cycle and classify inventory as either current or long-term on our balance sheet. We further consider inventory shelf life in our estimates regarding the net realizable value of our inventory. 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 routinely assess whether a valuation allowance should be established against our deferred tax assets based on consideration of all available evidence, both positive and negative, using a more likely than not standard. The assessment of the realizability of deferred tax assets requires management to make numerous estimates and assumptions. Factors that are considered in this assessment include the nature, frequency, and severity of recent losses; a forecast of future profitability; the duration of statutory carryback and carryforward periods; our experience with tax attributes expiring unused; and tax planning alternatives.

Stock-based compensation

We recognize compensation expense associated with the issuance of equity instruments to employees and non-employees for their services. Compensation expense is determined based on the grant date fair value and is expensed over the vesting period. The grant date fair value of stock options is measured using the Black-Scholes option valuation model. The input assumptions used in determining the fair value of options are expected life, expected volatility, risk-free interest rate and expected dividend yield. These input assumptions are based on management's estimates, and these estimates are evaluated periodically for reasonability. The expected life of the option represents the period the stock-based awards are expected to be outstanding. We use the simplified method for estimating the expected life of the options since we have limited historical experience to estimate expected term behavior. Since our common stock was not publicly traded until June 2018 there has been insufficient volatility data available. Accordingly, we calculate expected volatility using comparable peer companies with publicly traded shares over a term similar to the expected term of the options issued. Since we currently do not intend to pay dividends on our common stock, we estimate the dividend yield percentage to be zero. We base the risk-free interest rate on the U.S. Treasury constant maturity interest rate whose term is consistent with the expected life of the stock options being valued.

Loss contingencies

We are subject to claims and lawsuits in the ordinary course of business, including claims by employees or former employees, with respect to our products and involving commercial disputes, or shareholder actions. We accrue for loss contingencies when it is deemed probable that a loss has been incurred and the loss is estimable. The amounts accrued are based on the full amount of the estimated loss considering insurance proceeds, if applicable, and do not include legal fees expected to be incurred in connection with the loss contingency. The process of analyzing, assessing, and establishing reserve estimates relative to legal proceedings involves a high degree of judgment. Our consolidated financial statements do not reflect any material amounts related to unfavorable outcomes of claims and lawsuits to which we are currently a party because we currently believe that such claims and lawsuits are not expected to result in a material adverse effect on our financial condition. Management estimates that its current insurance coverage is sufficient to meet the potential liabilities of pending legal proceedings. Changes in facts and circumstances related to such proceedings could lead to significant adjustments to reserve estimates for such matters and could have a material impact on our results of operations, cash flows and financial condition in the period that reserve estimates are adjusted or paid.

Emerging Growth Company Status

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

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

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO (December 31, 2023), (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, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 with the changes in those items in dollars.

	Years ended December 31,		Change
	2021	2020	
	(in thousands)		
Net sales	$ 5,451.2	$ 3,495.8	$ 1,955.4
Cost of goods sold	1,385.0	1,737.5	(352.5)
Gross profit	4,066.2	1,758.3	2,307.9
Operating expenses:			
Research and development	2,535.9	4,201.3	(1,665.4)
Selling, general and administrative	21,573.4	21,840.9	(267.5)
Restructuring and other severance related charges	—	464.6	(464.6)
Total operating expenses	24,109.3	26,506.8	(2,397.5)
Loss from operations	(20,043.1)	(24,748.5)	4,705.4
Other (income) expense:			
Gain on extinguishment of debt	(1,422.2)	—	(1,422.2)
Gain on termination of joint venture	(549.3)	—	(549.3)
Interest and other income	(10.7)	(84.3)	73.6
Other expense	8.3	17.8	(9.5)
Total other (income) expense	(1,973.9)	(66.5)	(1,907.4)
Loss before income taxes	(18,069.2)	(24,682.0)	6,612.8
Benefit from income taxes	851.2	1,170.9	(319.7)
Net loss	(17,218.0)	(23,511.1)	6,293.1

Net Sales

Net sales for the year ended December 31, 2021 increased 56% as compared to the year ended December 31, 2020. The increase of $2.0 million is due to increased sales from the U.S. Department of Veteran Affairs, as well as increased sales from outside the United States, and our U.S. commercial channel. We expect that the majority of our 2022 fiscal year revenue will continue to come from the U.S. Department of Veterans Affairs and United Kingdom, however, we expect to increase revenue from our commercial channel through cash pay models via direct-to-consumer approaches through our online stores in the United States and United Kingdom. Further, we expanded our cash pay proposition to include direct to physician models within our traditional neurology headache specialists, as well as the wide range of medical providers who manage patients' headache conditions including primary care physicians, women's health, pain management, functional and integrative medicine professionals, as well as chiropractors, and PharmDs (Doctors of Pharmacy).

Gross Profit

Gross profit increased $2.3 million for the year ended December 31, 2021 compared to the year ended December 31, 2020. This increase was due to the increase in net sales, as well as an inventory charge of $0.4 million in 2020 for which there was a corresponding charge of $70,000 in 2021. Gross margin was 75% and 50% for the years ended December 31, 2021 and 2020, respectively. Excluding the 2021 and 2020 inventory charges, gross margin for the years ended December 31, 2021 and December 31, 2020 was 76% and 63%, respectively. The increase in gross margin, excluding the 2020 inventory charge, was largely due to the more favorable absorption of labor and overhead costs, and product mix. The selling of our products with longer periods of therapy, have had a favorable impact on our gross profit and gross margin. Gross profit and gross margin in 2022 will be largely dependent on revenue levels, product mix, and the pricing levels of our therapy.

Research and Development

Research and development expense of $2.5 million for the year ended December 31, 2021 decreased by $1.7 million, or 40%, as compared to 2020.

This reduction was primarily due to significant reductions in company sponsored clinical trial costs offset by targeted investments to support certain investigator-initiated trials, scientific publications and product development. We expect research and development expenses to increase in 2022 largely due to planned expenditures in connection with the next generation of our therapy delivery platform.

Selling, General and Administrative

Selling, general and administrative expense of $21.6 million for the year ended December 31, 2021 was consistent with the prior year. Excluding the $0.6 million write-off of an operating lease right of use asset in 2020, selling general and administrative expense was $21.2 million for the year ended December 31, 2020. We expect an increase in our 2022 selling, general, and administrative expense as we may make targeted investments to support our commercial efforts.

Restructuring and Other Severance Related Expenses

There were no restructuring and other severance related costs recorded during the year ended December 31, 2021. Restructuring and other severance related charges for the year ended December 31, 2020 of $464,606 consisted of severance related expenses in connection with personnel changes.

Other (Income) Expense

Other (income) expense for the year ended December 31, 2021 of 1.9 million primarily represents the gain of $1.4 million recorded in association with the forgiveness of the PPP Loan and the gain of $0.5 million recorded related to the termination of the joint venture in Australia. Interest and other income of $10,678 and $84,327 for the years ended December 31, 2021 and 2020, respectively, primarily consisted of interest earned on cash, cash equivalents and marketable securities.

Liquidity and Capital Resources

At December 31, 2021 our cash, cash equivalents, and marketable securities was $34.7 million compared to $22.6 million at December 31, 2020.

	December 31,	
	2021	2020
	(in millions)	
Net cash (used in) provided by		
Operating activities	$ (13.6)	$ (20.1)
Investing activities	$ 18.2	$ (8.0)
Financing activities	$ 25.7	$ 18.9

Operating Activities

Net cash used in operating activities was $13.6 million and $20.1 million for the years ended December 31, 2021 and 2020, respectively. The reduction in 2021 is primarily due to a decrease in our net loss from operations, and less cash being used for working capital components such as inventory and accounts payable.

Investing Activities

Net cash provided by investing activities was $18.2 million for the year ended December 31, 2021. For the year ended December 31, 2020, net cash used in investing activities was $8.0 million. This increase reflects the increase in funds received from the maturity of marketable securities partially offset by a decrease in our purchases of marketable securities during the current period.

Financing Activities

Net cash provided by financing activities was $25.7 million for the year ended December 31, 2021, representing net proceeds from the sale of common stock. For the year ended December 31, 2020, net cash provided by financing activities was $18.9 representing net cash proceeds of $17.5 million from the issuance of common stock and $1.4 million from our loan under the PPP.

Liquidity Outlook

As of December 31, 2021, our cash, cash equivalents and marketable securities totaled $34.7 million.

We have experienced recurring losses since our inception. We incurred net cash used in operating activities of $13.6 million and $20.1 million for the years ended December 31, 2021 and 2020, respectively. We expect to continue to incur substantial negative cash flows from operations for at least the next several years as we work to increase market acceptance of our gammaCore therapy for the acute treatment of primary headache and its other indications.

Our expected cash requirements for the next 12 months and beyond are largely based on the commercial success of our products and the level of targeted investment in our commercial strategies. There are significant risks and uncertainties as to our ability to achieve these operating results, including as a result of the adverse impact on its headache business from the ongoing COVID-19 pandemic. These conditions raise substantial doubt about our ability to continue as a going concern.

We have historically funded our operations from the sale of our common stock. During the year ended December 31, 2021, we received net proceeds of approximately $25.7 million from such sales and as of December 31, 2021, our cash, cash equivalents and marketable securities totaled $34.7 million.

We believe that the substantial doubt of our ability to continue as going concern is alleviated based on proceeds received from recent offerings of our common stock. We believe our cash and marketable securities will enable us to fund our operating expenses and capital expenditure requirements, as currently planned, for at least the next 12 months from the date the financial statements included in this Annual Report are made available.

Beyond the next 12 months, we believe that our growth will depend, in part, on our ability to fund our commercial efforts for our gammaCore therapy, and to opportunistically pursue research and development activities for additional indications for our gammaCore therapy. Our existing resources are unlikely to allow us to conduct all the activities that we believe could be beneficial for our future growth. As a result, we will need to seek additional funds in the future or curtail or forgo some or all such activities. If we seek to and are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. Changes, including those relating to the payer and competitive landscape, our commercialization strategy, our development activities and regulatory matters, may occur beyond our control that would cause us to consume our available capital more quickly.

On January 18, 2022, we filed a Form S-3 registration statement, or the 2022 Shelf Registration Statement, with the SEC, for the issuance of common stock, preferred stock, warrants, rights, debt securities and units, which we refer to collectively as the Shelf Securities, up to an aggregate amount of $75 million. The 2022 Shelf Registration Statement was declared effective on January 25, 2022.The proposed maximum offering price per unit and the proposed maximum aggregate offering price per class of security will be determined from time to time by us in connection with the issuance by us of the securities registered under the 2022 Shelf Registration Statement. Until such time as the aggregate market value of our securities held by non-affiliates equals or exceeds $75 million, the aggregate maximum offering price of all securities issued by the us in any given 12-calendar month period pursuant to this and any of our other registration statements may not exceed one-third of the aggregate market value of our securities held by non-affiliates.

Off-Balance Sheet Arrangements

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

Impact of Recently Issued Accounting Standards

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

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

We develop our products in the United States and sell those products into several 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 British Pound Sterling. 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, 2021

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

All of the potential changes noted above are based on sensitivity analyses performed on our financial position as of December 31, 2021.

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 9 A. 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, 2021 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, 2021, were effective for the purposes stated above.

Management's Report on Internal Control Over Financial Reporting

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

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

As of December 31, 2021, our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013). Based on this evaluation, our management concluded that, as of December 31, 2021 our internal control over financial reporting was effective.

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2021 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

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 2022 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 2022 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 2022 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 2022 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 Accountant 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 2022 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 and 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*****	Amended and Restated Bylaws of electroCore, Inc.
4.1*****	Registration Rights Agreement, dated March 27, 2020, between electroCore, Inc. and Lincoln Park Capital Fund, LLC
4.2*	Description of Capital Stock
10.2†**	electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.3†*	Form of Employee Restricted Stock Unit Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.4†*	Form of Non-qualified Stock Option Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.5†**	Form of Employee Restricted Stock Award Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.6†**	Form of Non-Employee Director Inaugural Deferred Stock Unit Award Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.7†**	Form of Non-Employee Director Inaugural Non-qualified Stock Option Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.8†**	Form of Non-Employee Director Inaugural Restricted Stock Unit Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.9†**	Form of Non-Employee Director Annual Deferred Stock Unit Award Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.10†**	Form of Non-Employee Director Annual Non-qualified Stock Option Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.11†**	Form of Non-Employee Director Annual Restricted Stock Unit Agreement for electroCore, Inc. 2018 Omnibus Equity Incentive Plan
10.12†**	Form of Indemnification Agreement between the Registrant and each of its executive officers and directors
10.13†**	Form of electroCore, Inc. Management Severance Plan
10.14†*	electroCore, Inc. Non-Employee Director Compensation Policy
10.15****	Rockaway, NJ Office Lease between Anson Logistics Assets LLC and electroCore, Inc.
10.17**	Form of Common Unit Warrant
10.18**	Form of Series A Warrant
10.19**	Form of Bridge Warrant

10.20†	Employment Offer Letter, dated as of September 26, 2019, between electroCore, Inc. and Daniel Goldberger, incorporated by reference to the Company's Current Report on Form 8-K, as filed with the Commission on October 2, 2019.
10.21†	Brian Posner Employment Agreement, dated as of January 30, 2019, incorporated by reference to the Company's Current Report on Form 8-K, as filed with the Commission on March 12, 2019.
10.22†	Amendment to Brian Posner Employment Agreement, dated as of August 8, 2019, incorporated by reference to the Company's Quarterly Report on Form 10-Q, as filed with the Commission on August 14, 2019.
21.1*	List of subsidiaries of electroCore, Inc.
23.1*	Consent of Marcum 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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline 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, 2019 as filed with the Commission on August 14, 2019.
****	Incorporated by reference to the Company’s Annual Report on Form 10-K for the period ended December 31, 2018 as filed with the Commission on March 28, 2019.
*****	Incorporated by reference to the Company’s Current Report on Form 8-K as filed with Commission on March 27, 2020.
******	Incorporated by reference to the Company's Current Report on Form 8-K as filed with Commission on December 23, 2021
†	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 10, 2022 By: /s/ DANIEL S. GOLDBERGER

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

Date: March 10, 2022 By: /s/ BRIAN M. POSNER

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

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

Name	Title	Date
/s/ Peter Cuneo **Peter Cuneo**	Chairman of the Board	March 10, 2022
/s/ Michael G. Atieh **Michael G. Atieh**	Director	March 10, 2022
/s/ Daniel S. Goldberger **Daniel S. Goldberger**	Director	March 10, 2022
/s/ John Gandolfo **John Gandolfo**	Director	March 10, 2022
/s/ Joseph P. Errico **Joseph P. Errico**	Director	March 10, 2022
/s/ Thomas Patton **Thomas Patton**	Director	March 10, 2022
/s/ Thomas J. Errico, M.D. **Thomas J. Errico, M.D.**	Director	March 10, 2022
/s/ Trevor J. Moody **Trevor J. Moody**	Director	March 10, 2022

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
electroCore, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of electroCore, Inc. and Subsidiaries (the “Company”) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, equity and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company’s auditor since 2020.

New York, NY
March 10, 2022

ELECTROCORE, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 34,688,880	$ 4,241,937
Marketable securities	—	18,386,160
Accounts receivable, net	438,243	270,546
Inventories, net	1,360,594	876,436
Prepaid expenses and other current assets	1,053,572	1,288,588
Total current assets	37,541,289	25,063,667
Inventories, noncurrent	3,940,055	4,865,181
Property and equipment, net	146,568	244,047
Operating lease right of use assets, net	613,280	517,257
Other assets, net	591,518	828,011
Total assets	$ 42,832,710	$ 31,518,163
Liabilities and Equity		
Current liabilities:		
Accounts payable	$ 1,543,032	$ 2,078,699
Accrued expenses and other current liabilities	3,880,978	2,965,702
Note payable, current	—	311,354
Current portion of operating lease liabilities	61,403	534,547
Total current liabilities	5,485,413	5,890,302
Operating lease liabilities, noncurrent	699,463	885,333
Note payable, noncurrent	—	1,097,946
Total liabilities	6,184,876	7,873,581
Commitments and contingencies (Note 17)	—	—
Stockholders' equity:		
Preferred Stock, par value $0.001 per share; 10,000,000 shares authorized as of December 31, 2021 and December 31, 2020; 0 shares issued and outstanding as of both December 31, 2021 and December 31, 2020	—	—
Common Stock, par value $0.001 per share; 500,000,000 shares authorized as of both December 31, 2021 and 2020; 70,704,123 shares issued and outstanding at December 31, 2021, and 45,559,765 shares issued and outstanding at December 31, 2020	70,704	45,560
Additional paid-in capital	160,772,600	130,205,027
Accumulated deficit	(124,208,218)	(106,990,148)
Accumulated other comprehensive income (loss)	12,748	(251,467)
Total stockholders' equity	36,647,834	23,008,972
Noncontrolling interest	—	635,610
Total equity	36,647,834	23,644,582
Total liabilities and equity	$ 42,832,710	$ 31,518,163

See accompanying notes to the consolidated financial statements.

ELECTROCORE, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

	Years ended December 31,	
	2021	2020
Net sales	$ 5,451,192	$ 3,495,832
Cost of goods sold	1,385,003	1,737,539
Gross profit	4,066,189	1,758,293
Operating expenses:		
Research and development	2,535,864	4,201,279
Selling, general and administrative	21,573,431	21,840,919
Restructuring and other severance related charges	—	464,606
Total operating expenses	24,109,295	26,506,804
Loss from operations	(20,043,106)	(24,748,511)
Other (income) expense:		
Gain on extinguishment of debt	(1,422,214)	—
Gain on termination of joint venture	(549,254)	—
Interest and other income	(10,678)	(84,327)
Other expense	8,280	17,756
Total other income	(1,973,866)	(66,571)
Loss before income taxes	(18,069,240)	(24,681,940)
Benefit from income taxes	851,170	1,170,890
Net loss	$ (17,218,070)	$ (23,511,050)
Net loss per share of common stock - Basic and Diluted (see Note 13)	$ (0.29)	$ (0.60)
Weighted average common shares outstanding - Basic and Diluted (see Note 13)	59,177,718	38,998,698

See accompanying notes to the consolidated financial statements.

ELECTROCORE, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

	Years ended December 31,	
	2021	2020
Net loss	$ (17,218,070)	$ (23,511,050)
Other comprehensive income (loss):		
Foreign currency translation adjustment	175,470	(207,012)
Foreign currency translation adjustment - deconsolidation	86,356	—
Unrealized gain (loss) on marketable securities, net of taxes as applicable	2,389	(3,160)
Other comprehensive income (loss)	264,215	(210,172)
Comprehensive loss	$ (16,953,855)	$ (23,721,222)

See accompanying notes to consolidated financial statements.

ELECTROCORE, INC. AND SUBSIDIARIES

Consolidated Statements of Equity
For the Years Ended December 31, 2021 and 2020

	Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total electroCore, Inc., stockholders' equity	Noncontrolling interest	Total equity
	Shares	Amount						
Balances as of December 31, 2019	29,835,183	29,835	107,752,066	(83,479,098)	(41,295)	24,261,508	635,610	24,897,118
Net loss	—	—	—	(23,511,050)	—	(23,511,050)	—	(23,511,050)
Other comprehensive income	—	—	—	—	(210,172)	(210,172)	—	(210,172)
Issuance of stock (see Note 12)	14,308,048	14,308	19,370,888	—	—	19,385,196	—	19,385,196
Equity financing commitment fee*	692,514	693	(693)	—	—	—	—	—
Financing fees	—	—	(182,821)	—	—	(182,821)	—	(182,821)
Issuance of common stock in connection with employee stock plans, net of forfeitures	724,020	724	(724)	—	—	—	—	—
Share based compensation	—	—	3,266,311	—	—	3,266,311	—	3,266,311
Balances as of December 31, 2020	45,559,765	45,560	130,205,027	(106,990,148)	(251,467)	23,008,972	635,610	23,644,582
Net loss	—	—	—	(17,218,070)	—	(17,218,070)	—	(17,218,070)
Other comprehensive income	—	—	—	—	264,215	264,215	—	264,215
Issuance of stock (see Note 12)	23,450,000	23,450	25,658,712	—	—	25,682,162	—	25,682,162
Issuance of stock to satisfy certain obligations (see Note 12)	1,152,380	1,152	1,207,323	—	—	1,208,475	—	1,208,475
Issuance of common stock in connection with employee stock plans, net of forfeitures	376,565	377	(377)	—	—	—	—	—
Settlement of accrued bonus	165,413	165	399,832	—	—	399,997	—	399,997
Share based compensation	—	—	3,302,083	—	—	3,302,083	—	3,302,083
Termination of joint venture	—	—	—	—	—	—	(635,610)	(635,610)
Balances as of December 31, 2021	70,704,123	$ 70,704	$ 160,772,600	$ (124,208,218)	$ 12,748	$ 36,647,834	$ —	$ 36,647,834

*Reflects commitment shares issued in accordance with the Company's equity facility purchase agreement with Lincoln Park Capital. For additional information see Note 12. Stockholders' Equity, Lincoln Park Purchase Agreement.

See accompanying notes to the consolidated financial statements.

ELECTROCORE, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (17,218,070)	$ (23,511,050)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	3,302,083	3,266,311
Depreciation and amortization	381,509	399,242
Amortization of marketable securities premium	142,244	31,096
Gain on extinguishment of debt	(1,422,214)	—
Gain on termination of joint venture	(549,254)	—
Gain on lease settlement	(57,371)	—
Increase in allowance for doubtful accounts	49,489	—
(Gain) loss on legal fee obligation settled with stock	(9,525)	156,434
Noncash lease expense	55,114	372,304
Inventory reserve charge	69,972	433,918
Write-off of right of use operating lease asset	—	557,543
Other	—	676
Changes in operating assets and liabilities:		
Accounts receivable	(217,186)	225,594
Inventories	370,996	735,637
Prepaid expenses and other assets	716,044	982,129
Accounts payable	464,333	(1,581,579)
Accrued expense and other current liabilities	425,219	(1,632,617)
Right of use operating lease assets	(151,137)	—
Operating lease liabilities	20,131	(486,445)
Net cash used in operating activities	(13,627,623)	(20,050,807)
Cash flows from investing activities:		
Purchase of marketable securities	(5,082,730)	(24,463,158)
Proceeds from maturities of marketable securities	23,300,000	16,500,000
Net cash provided by (used in) investing activities	18,217,270	(7,963,158)
Cash flows from financing activities:		
Proceeds from shares issued, net of related expenses	25,682,162	17,489,563
Proceeds from note issued	—	1,410,524
Net cash provided by financing activities	25,682,162	18,900,087
Effect of changes in exchange rates on cash and cash equivalents	175,134	(207,976)
Net increase (decrease) in cash and cash equivalents	30,446,943	(9,321,854)
Cash and cash equivalents – beginning of year	4,241,937	13,563,791
Cash and cash equivalents – end of year	$ 34,688,880	$ 4,241,937
Supplemental cash flows disclosures:		
Proceeds from sale of state net operating losses	$ 876,690	$ 1,170,890
Income taxes paid	$ 38,622	$ 3,769
Interest paid	$ 9,941	$ 12,895
Supplemental schedule of noncash activity:		
Settlement of certain obligations through issuance of common stock	$ 1,275,370	$ 1,548,702
2020 bonus paid in stock	$ 399,997	$ —

See accompanying notes to consolidated financial statements.

Note 1. The Company

electroCore is commercial stage medical device company with a proprietary non-invasive vagus nerve stimulation, or nVNS, therapy, called gammaCore. nVNS is a platform bioelectronic medical therapy that modulates neurotransmitters and immune function through its effects on both the peripheral and central nervous systems. The Company is initially focused on utilizing gammaCore in the management and treatment of primary headache conditions.

electroCore, headquartered in Rockaway, New Jersey, has two wholly owned subsidiaries: electroCore Germany GmbH, and electroCore UK Ltd. The Company has ceased its operations in Germany, although sales to Germany are still supported by electroCore UK Ltd. On November 2, 2021, the Company formally terminated its agreement with electroCore (Aust) Pty Limited (“electroCoreAustralia”). Prior to this termination, electroCoreAustralia was subject to electroCore’s control on a basis other than voting interests and was a variable interest entity (“VIE”), for which electroCore was the primary beneficiary. As of May 2017, the VIE had ceased operations. (see Note 14)

Note 2. Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements were prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”), and the rules and regulations of the Securities and Exchange Commission ("SEC").

(b) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of electroCore and its wholly owned subsidiaries. electroCore Australia was consolidated with the non-controlled equity presented as non-controlling interest in the Company's consolidated financial statements for the year ended December 31, 2020. As described in Note 1, the Company terminated its affiliation with electroCore Australia on November 2, 2021 and, as such, this dormant entity was not included in the Company's consolidated financial statements for the year ended December 31, 2021. All intercompany balances and transactions have been eliminated in consolidation.

(c) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP 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 allowances for doubtful accounts, trade credits, rebates, co-payment assistance and sales returns, valuation of inventory, stock compensation, incremental borrowing rate and contingencies.

(d) Revenue Recognition

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

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

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

(e) Cash and Cash Equivalents

Cash and cash equivalents include all highly liquid investments with a maturity of three months or less when purchased. The Company’s accounts are insured by the Federal Deposit Insurance Corporation (“FDIC”) up to $250,000 per financial institution in the United States, and up to £85,000 by the Financial Services Compensation Scheme (“FSCS”) per financial institution in the United Kingdom.

(f) Marketable Securities

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

(g) Concentration of Credit Risk

Cash, cash equivalents and marketable securities are financial instruments that potentially subject the Company to concentration of credit risk. As of December 31, 2021, the Company's cash equivalents and marketable securities were largely comprised of money market funds. 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. As of December 31, 2021, approximately 99.2% of the Company's cash, cash equivalents and marketable securities was denominated in U.S. Dollars, the balance is subject to foreign exchange risk.

(h) Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company maintains an allowance for doubtful accounts for estimated losses inherent in its accounts receivable portfolio. Management considers an account receivable to be past due when it is not settled under its stated terms. In establishing the required allowance, management considers historical losses adjusted to take into account current market conditions and customers financial condition, the amount of receivables in dispute, and the current receivables aging and current payment patterns. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. During the years ended December 31, 2021 and 2020, the Company's allowance for doubtful accounts was immaterial. The Company does not have any off balance sheet credit exposure related to its customers.

(i) Inventories

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

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

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

(j) Property and Equipment

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

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

Machinery and equipment	3–15 years
Leasehold improvements	Lesser of estimated useful life or remaining term of lease
Furniture and fixtures	5–10 years
Computer equipment	5 years

(k) Leases

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

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

(l) Cloud Computing Arrangement

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

(m) Impairment of Long-Lived Assets

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

(n) Stock-based Compensation

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

(o) Income Taxes

The Company follows the asset and liability method of accounting for income taxes under ASC 740, "Income Taxes." Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax provisions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company is currently not aware of any issues under review that could result in significant payments, accruals or deviation from its position during the next twelve months.

(p) Research and Development

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

(q) Foreign Currency Translation and Transactions

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

(r) Segment Information

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

(s) Revision of Statement of Cash Flows Activity

In preparation of its financial statements for the quarter ended March 31, 2021, the Company realized that proceeds from its July 1, 2020 Commercial Insurance Premium Finance and Security Agreement should have been treated as a noncash activity instead of grossed up on the accompanying consolidated statement of cash flows. Even though the amount was not considered material, the financial statements have been revised. As a result, net cash used in operating and provided by financing activities for the year ended December 31, 2020, decreased by approximately $52,000.

(t) Prior year presentation

Prior year presentation has been conformed to current year presentation.

(u) Recently Adopted Accounting Standards

In August 2018, the FASB issued guidance which modified the disclosure requirements for fair value measurements. The guidance is effective for the year ended December 31, 2020. The Company adopted this guidance, and it was properly reflected in the consolidated financial statements. The impact on the consolidated financial statements was immaterial.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326); Measurement of Credit Losses on Financial Instruments, ASU 2016-13 changes the impairment model for most financial assets, including trade and other receivables, from an incurred loss method to a new forward looking approach based on expected losses. The new approach includes the consideration of historical experience, current conditions, and reasonable and supportable forecasts. The Company adopted this guidance and determined the impact on the consolidated financial statements was immaterial.

In December 2019, the FASB issued an update to simplify the accounting for income taxes and improve consistent application by clarifying or amending existing guidance. This guidance is effective for the year ended December 31, 2021. The Company adopted this guidance and determined the impact on the consolidated financial statements was immaterial.

Note 3. Significant Risks and Uncertainties

Liquidity

The Company has experienced significant net losses and cash used in operations, and it expects to continue to incur net losses and cash used in operations for the near future as it works to increase market acceptance of its gammaCore. The Company has never been profitable and has incurred net losses and cash used in operations in each year since its inception. The Company incurred net losses of $17.2 million and $23.5 million for the years ended December 31, 2021 and 2020, respectively. Cash used in operating activities was $13.6 million and $20.1 million for the years ended December 31, 2021 and 2020, respectively.

The Company's expected cash requirements for the next 12 months and beyond are largely based on the commercial success of its products. There are significant risks and uncertainties as to its ability to achieve these operating results, including as a result of the adverse impact on its headache business from the ongoing COVID-19 pandemic. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company has historically funded its operations from the sale of its common stock. During the year ended December 31, 2021, the Company received net proceeds of approximately $25.7 million from such sales and as of December 31, 2021, the Company's cash, cash equivalents and marketable securities totaled $34.7 million. The Company believes that the substantial doubt of its ability to continue as a going concern is alleviated based on proceeds received from its common stock offerings. The Company believes its cash and marketable securities will enable it to fund its operating expenses and capital expenditure requirements, as currently planned, for at least the next 12 months from the date the accompanying financial statements are issued.

Concentration of Revenue Risks

The Company earns a significant amount of its revenue (i) in the United States from the Department of Veterans Affairs and Department of Defense ("VA/DoD") pursuant to its qualifying contract under the Federal Supply Schedule and open market sales to individual Department of Veterans Affairs facilities and (ii) in the United Kingdom from the National Health Service. Each of these two channels accounted for 10% or more of the Company's net sales in the years ended December 31, 2021 and 2020. The following table reflects the respective concentration as a percentage of the Company's total net sales:

	Years ended December 31,	
	2021	2020
Revenue channel:		
VA/DoD	59.8 %	57.9%
National Health Service	24.1 %	29.0%

The following table reflects the Company's net sales concentration within the VA/DoD:

	Years ended December 31,	
	2021	2020
Number of VA/DoD facilities	4	4
VA/DoD net sales concentration	51.4 %	45.3 %
Number of VA/DoD facilities accounting for more than 10% of VA/DoD net sales	2	2

During these periods, no other customer accounted for 10% or more of the Company's net sales.

Foreign Currency Exchange Risks

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

COVID-19 Risks and Uncertainties

The Company continues to monitor the impact of the coronavirus pandemic on all aspects of its business and geographies, including how it will impact business partners, customers and the global supply chain. While the Company experienced disruptions during the years ended December 31, 2021 and 2020 from the coronavirus pandemic, it is unable to predict the full impact that the coronavirus pandemic may have on its financial condition, results of operations and cash flows due to numerous uncertainties. These uncertainties include the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. The coronavirus pandemic has significantly adversely impacted global economic activity and has contributed to significant volatility and negative pressure in financial markets. Depending upon the duration and severity of the pandemic, the continuing effect on the Company's results and outlook over the long term remains uncertain.

Note 4. Revenue Recognition

Geographical Net Sales

The following table presents net sales disaggregated by geographic area:

	Years ended December 31,	
	2021	2020
Geographic Market		
United States	$ 3,939,862	$ 2,374,687
United Kingdom	1,343,981	1,051,206
Germany	28,993	53,925
Other	138,356	16,014
Total Net Sales	$ 5,451,192	$ 3,495,832

Performance Obligations

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

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

Trade credits are discounts that are contingent upon a timely remittance of payment and are estimated based on historical experience. For the years ended December 31, 2021 and 2020, trade credits and discounts 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 Company’s contracts with customers did not give rise to contract assets or liabilities during the year ended December 31, 2021 and 2020.

Agreed upon payment terms with customers are within 30 days of shipment. Accordingly, contracts with customers do not include a significant financing component.

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, 2021 and 2020.

As of December 31, 2021

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 34,688,880	$ —	$ —	$ 34,688,880
U.S. Treasury Bonds	421	—	(421)	—
Total marketable securities	$ 421	$ —	$ (421)	$ —
Total cash, cash equivalents and marketable securities	$ 34,689,301	$ —	$ (421)	$ 34,688,880

As of December 31, 2020

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 4,241,937	$ —	$ —	$ 4,241,937
U.S. Treasury Bonds	18,388,970	—	(2,810)	18,386,160
Total marketable securities	$ 18,388,970	$ —	$ (2,810)	$ 18,386,160
Total cash, cash equivalents and marketable securities	$ 22,630,907	$ —	$ (2,810)	$ 22,628,097

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

Note 6. Fair Value Measurements

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

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

As of December 31, 2020, the Company's Marketable securities (U.S. treasury bonds) in the amount of $18,386,160 were carried at fair value in accordance with Level 1 as described above. The Company had no financial assets or liabilities as of December 31, 2021 that required valuation in accordance with the Levels described above. 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, 2021 and 2020. The carrying amount of the Company's receivables and payables approximate their fair value due to their maturity.

Note 7. Inventory

As of December 31, 2021 and 2020, inventories consisted of the following:

	December 31,	
	2021	2020
Raw materials	$ 768,862	$ 1,008,653
Work in process	4,071,516	4,304,415
Finished Goods	460,271	428,549
Total Inventory	5,300,649	5,741,617
Less: noncurrent inventory	3,940,055	4,865,181
Total current inventory	$ 1,360,594	$ 876,436

As of December 31, 2021 and 2020, the Company reserved $821,012 and $721,462 respectively, for obsolete inventory. The Company records charges for obsolete inventory in cost of goods sold. As of December 31, 2021 and 2020, noncurrent inventory was comprised of approximately $0.9 million and $0.7 million of raw materials, respectively, and $3.0 million and $4.2 million of work in process, respectively. Inventory classified under the category Work in process consists of prefabricated assembled product.

Note 8. Leases

The Company accounts for leases in accordance with FASB ASU 2016-02, Leases (Topic 842), and its operating leases consist of office space, manufacturing/warehouse space, and office equipment. The Company elected not to recognize right of use assets and lease liabilities for short term leases, i.e., leases with a noncancelable period of 12 months or less. The Company recognized the option to renew its manufacturing/warehouse space ("Rockaway space") as part of the right of use asset and the lease liability as the Company deemed that the renewal option was reasonably certain to be exercised.

In connection with its cost reduction strategies, the Company vacated its New Jersey corporate headquarters ("Basking Ridge office space") and relocated its corporate headquarters to the Rockaway space effective December 31, 2020. Although the Basking Ridge lease agreement provided for sublease, the Company did not elect this option in light of the economic downturn in commercial real estate due to the pandemic and other factors. In December 2020, the Company informed the Basking Ridge landlord of its intention to vacate the Basking Ridge office space on December 31, 2020.

On December 31, 2020, the Company wrote off the net book value of the operating lease right of use asset associated with the Basking Ridge office space in the amount of $534,493 along with the related asset balances totaling $23,050. This charge is reflected in the Company's Consolidated Statement of Operations for the year ended December 31, 2020, under selling, general and administrative expense.

On September 27, 2021, the Company entered into the Termination and Settlement Agreement ("Agreement") with the lessor of the Basking Ridge office space. The Agreement provided for the immediate termination of the Basking Ridge lease in its entirety. In consideration for the lease termination, the Company agreed to pay the lessor a total of $500,000 in cash and issue to the lessor 200,000 shares of its common stock. As of December 31, 2021, such payments were satisfied by the Company. The Company recorded a gain of $57,371 in connection with the termination of the Agreement which is included in the accompanying Consolidated Statements of Operations for the year ended December 31, 2021 under the caption Operating expenses - Selling, general and administrative.

For the years ended December 31, 2021 and 2020, the Company recognized lease expense of $146,236 and $573,046, respectively. This expense does not include non-lease components associated with the lease agreements as the Company elected not to include such charges as part of the lease expense.

Supplemental Balance Sheet Information for Operating Leases:

	December 31,	
	2021	2020
Operating leases:		
Operating lease right of use assets	$ 613,280	$ 517,257
Operating lease liabilities:		
Current portion of operating lease liabilities	61,403	534,547
Noncurrent operating lease liabilities	699,463	885,333
Total operating lease liabilities	$ 760,866	$ 1,419,880
Weighted average remaining lease term (in years)	6.9	5.7
Weighted average discount rate	13.8%	13.8%

Future minimum lease payments under non-cancellable operating leases as of December 31, 2021:

Financial year	
2022	$ 160,486
2023	163,962
2024	167,524
2025	171,180
2026	160,602
2027 and thereafter	373,118
Total future minimum lease payments	1,196,872
Less: Amounts representing interest	(436,006)
Total	$ 760,866

Note 9. Cloud Computing Arrangement

In 2018, the Company entered into a contract to obtain a cloud computing arrangement ("CCA"). In accordance with ASU 2018-15, the implementation costs incurred in the CCA were deferred and recognized as other assets and are being amortized to expense over the noncancelable term of the arrangement. The implementation of this CCA was completed on June 30, 2019. Beginning July 1, 2019, the Company went live with the cloud computing Enterprise Resource Planning system and all future related costs are expensed as incurred. In July 2019, the Company began amortizing the related deferred costs over the remaining period of the noncancelable arrangement. Amortization costs for the years ended December 31, 2021 and 2020 were $282,074 and $282,074, respectively. As of December 31, 2021, the remaining term of the lease is approximately two years. The CCA is included in the accompanying Consolidated Balance Sheet for the years ended December 31, 2021 and 2020 under the caption Other assets, net, and is summarized below:

	December 31,	
	2021	2020
Cloud Computing Arrangement	$ 1,222,322	$ 1,222,322
Less: accumulated amortization	705,186	423,112
Cloud Computing Arrangement, net	$ 517,136	$ 799,210

Note 10. Accrued Expenses and Other Current Liabilities

Accrued expenses as of December 31, 2021 and 2020 consisted of the following:

	December 31,	
	2021	2020
Accrued professional fees	$ 468,101	$ 270,543
Accrued bonuses and incentive compensation	1,849,159	1,424,878
Accrued insurance expense	499,195	164,832
Other employee related expenses	455,110	371,033
Miscellaneous taxes payable	262,515	243,245
Other	346,898	491,171
	$ 3,880,978	$ 2,965,702

Finance and Security Agreements

On July 2, 2021, the Company entered into a Commercial Insurance Premium Finance and Security Agreement ("the 2021 Agreement"). The 2021 Agreement provides for a single borrowing by the Company of $1.2 million, with a ten-month term and an annual interest rate of 1.55%. The proceeds from this transaction were used to partially fund the premiums due under some of the Company's insurance policies. The amounts payable are secured by the Company's rights under such policies. The Company began to pay monthly installments of approximately $124,800 beginning in July 2021. As of December 31, 2021, the remaining balance under the Agreement was $499,195 and during the year ended December 31, 2021, the Company recognized $5,292 in interest expense.

On July 1, 2020, the Company entered into a Commercial Insurance Premium Finance and Security Agreement ("the 2020 Agreement"). The 2020 Agreement provides for a single borrowing by the Company of $1.2 million, with a seven-month term and an annual interest rate of 2.18%. The proceeds from this transaction were used to partially fund the premiums due under some of the Company's insurance policies. All borrowings related to the 2020 Agreement were fully repaid as of December 31, 2021.

Note 11. Note Payable

Paycheck Protection Program

On May 4, 2020, the Company received proceeds of $1.4 million in connection with a promissory note (the “Note”) entered into with Citibank, N.A. (the “Lender”) evidencing an unsecured loan (the “Loan”) under the Paycheck Protection Program ("PPP"). The PPP is a program of the SBA established under the CARES Act. Under the PPP, the proceeds of the Loan may be used for payroll and certain covered interest payments, lease payments and utility payments (“Qualifying Expenses”). The Company used the entire Loan amount for Qualifying Expenses under the PPP.

On May 18, 2021, the Company received notification from the Lender of SBA's approval of the Company's application for loan forgiveness. Accordingly, the Company was not required to repay the loan. The Company has recorded the loan forgiveness as a gain in the accompanying Consolidated Statements of Operations for the year ended December 31, 2021 under the caption Gain on extinguishment of debt.

Note 12. Stockholders’ Equity

Public Offering of Common Stock

On July 2, 2021, the Company completed a public offering of 20,700,000 shares of its common stock at a purchase price of $1.00 per share. The net proceeds of the offering to the Company were approximately $18.8 million, after deducting the underwriting discounts, commissions, and other offering expenses.

Other 2021 Securities Purchase Agreements

On August 30, 2021, the Company entered into a Securities Purchase Agreement with its legal counsel pursuant to which the Company issued 952,380 shares of common stock, at a purchase price of $1.05 per share. Upon issuance of the shares, certain of the Company's outstanding financial obligations to its legal counsel were deemed paid and satisfied in full.

Settlement of Lease Liability

During 2021, the Company agreed to issue 200,000 shares of its common stock in connection with the lease termination related to its former headquarters located in Basking Ridge, NJ.

Settlement of Accrued Bonus

In January 2021, the Company issued 165,413 shares of its common stock as payment for certain executive incentive bonuses accrued in 2020.

Lincoln Park Purchase Agreement

On March 27, 2020, the Company and Lincoln Park entered into an equity facility purchase agreement ("Purchase Agreement") pursuant to which the Company has the right to sell to Lincoln Park shares of common stock having an aggregate value of up to $25,000,000, subject to certain limitations and conditions set forth in the purchase agreement.

Upon entering into the Purchase Agreement with Lincoln Park, the Company issued an aggregate of 461,676 shares of common stock to Lincoln Park as a commitment fee. The fair value of these shares on the date of issuance was approximately $186,300. During 2020, the Company issued an additional 230,838 shares of common stock to Lincoln Park as a further commitment fee based on the first $5,000,000 of shares of common stock issued to Lincoln Park under the Purchase Agreement as Purchase Shares (as such term is defined in the Purchase Agreement). The Company did not receive any cash proceeds from the issuance of any of the foregoing commitment shares. No further commitment fee shares remain issuable under the Purchase Agreement. The net proceeds under the Purchase Agreement to the Company will depend on the frequency and prices at which shares of common stock are sold to Lincoln Park. Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement and the amount of such net proceeds will depend on a variety of factors, including market conditions, the trading price of the common stock and determinations by the Company as to other available and appropriate sources of funding for the Company. The Company has and expects to continue to use the proceeds from this agreement for general corporate purposes and working capital.

During 2020, the Company sold 10,179,676 shares of common stock under the Purchase Agreement, resulting in aggregate proceeds of approximately $15.5 million to the Company. In January 2021, the Company sold an additional 2,750,000 shares of its common stock under the Purchase Agreement, resulting in aggregate proceeds of approximately $6.9 million to the Company. On March 11, 2021, the Company terminated the Purchase Agreement and, accordingly, the Company will not sell any further shares of its common stock to Lincoln Park under the Purchase Agreement.

Other 2020 Securities Purchase Agreements

On April 14, 2020, the Company entered into a Securities Purchase Agreement ("First SPA") with certain accredited investors pursuant to which the Company agreed to sell an aggregate of 2,058,822 shares of common stock at a purchase price of $0.85 per share for aggregate proceeds to the Company of approximately $1.75 million. Each of the purchasers was an affiliate and/or existing shareholder of the Company, including some members of the Company's board of directors. In addition, the purchasers were granted customary registration rights as further described in the First SPA.

On May 14, 2020, the Company entered into a Securities Purchase Agreement ("Second SPA") with its legal counsel pursuant to which the Company agreed to issue 1,564,345 shares of common stock, at a purchase price of $0.99 per share. Upon issuance of the shares, certain outstanding financial obligations of the Company owed to its legal counsel were deemed paid and satisfied in full. In addition, the Company's legal counsel was granted customary registration rights as further described in the Second SPA. During 2020, the Company recorded a non-cash charge of $156,434 in connection with this transaction.

On May 18, 2020, the Company entered into a third Securities Purchase Agreement ("Third SPA") with certain accredited investors pursuant to which the Company agreed to sell an aggregate of 505,205 shares of common stock at a purchase price of $0.9178 per share, for aggregate proceeds to the Company of approximately $0.45 million. In addition, the purchasers were granted customary registration rights as further described in the Third SPA.

Stock Purchase Warrants

The following table presents a summary of stock purchase warrants outstanding as of December 31, 2021:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2021	715,199	$ 12.39	0.9	$ —
Granted	—	—		$ —
Exercised	—	—		$ —
Expired	(498,255)	12.54		$ —
Outstanding, December 31, 2021	216,944	$ 12.04	0.80	$ —
Exercisable, December 31, 2021	—	$ —	—	$ —

Note 13. Net Loss Per Share

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

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

	December 31,	
	2021	2020
Outstanding stock options	5,136,679	3,815,585
Nonvested restricted stock and unit awards	1,084,649	1,039,768
Stock purchase warrants	216,944	715,199
	6,438,272	5,570,552

Note 14. Variable Interest Entity

As discussed in Note 1, electroCore was the primary beneficiary of electroCore (Aust) Pty Limited ("electroCoreAustralia"). 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 had the right to appoint two of the four directors and exercise significant influence. This along with the fact that electroCore was electroCoreAustralia's only supplier caused electroCore, for accounting purposes, to be the primary beneficiary of electroCoreAustralia. The activities related to electroCoreAustralia were not material to the Company's consolidated financial statements. Effective May 2017, the VIE had ceased operations. On November 2, 2021, the Company terminated its interest in electroCoreAustralia and recorded the related a gain of $549,254 in the accompanying Consolidated Statement of Operations for the year ended December 31, 2021 under the caption Gain on termination of joint venture.

Note 15. Income Taxes

The benefit for income taxes for the years ended December 31, 2021 and 2020 consisted of foreign taxes, state minimum tax and a benefit from the sale of state net operating losses.

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

	December 31, 2021	December 31, 2020
Domestic	$ (16,679,171)	$ (23,706,567)
Foreign	(1,390,069)	(975,373)
Total	$ (18,069,240)	$ (24,681,940)

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

	December 31, 2021	December 31, 2020
Federal	$ —	$ —
State	(870,323)	(1,170,890)
Foreign	19,153	—
Total current	(851,170)	(1,170,890)
Total deferred	—	—
Total income tax benefit	$ (851,170)	$ (1,170,890)

The Company has evaluated the available evidence supporting the realization of its deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that its net deferred tax assets will not be realized in the United States and certain foreign jurisdictions. Due to uncertainties surrounding the realization of the deferred tax assets, the Company maintains a full valuation allowance against all of its net deferred tax assets. When the Company determines that it will be able to realize some portion or all of its deferred tax assets, an adjustment to its valuation allowance on its deferred tax assets would have the effect of increasing net income in the period such determination is made. The net change in the valuation allowance was an increase of $3.9 million.

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

	Year ended December 31,	
	2021	2020
Deferred tax assets		
Net operating loss carryforwards	$ 26,924,101	$ 24,319,202
Accrued expenses	579,321	540,072
Intangibles	468,716	429,783
Inventory	216,120	202,580
Allowance for bad debt	3,139	—
Deferred rent	—	27,019
Charitable contributions	10,572	11,277
R&D credit	429,784	438,117
Deferred FICA Tax	6,942	—
Lease liabilities	200,288	398,689
Stock compensation	4,429,809	3,069,124
Deferred tax assets	33,268,792	29,435,863
Less valuation allowance	(32,867,581)	(28,974,378)
Total deferred tax assets	401,211	461,485
Fixed assets	(5,856)	(16,119)
Prepaid expenses	(233,917)	(300,125)
Right of use asset	(161,438)	(145,241)
Total deferred tax liabilities	(401,211)	(461,485)
Deferred tax assets, net	$ —	$ —

A reconciliation of the income tax provision computed at statutory rates to the reported income tax provision for the years ended December 31, 2021 and 2020 is as follows:

	Year ended December 31,	
	2021	2020
Statutory rate	(21.0)%	(21.0)%
State tax expected (recovery), net of federal benefit	5.7%	(4.2)%
Stock compensation	(5.7)%	(6.8)%
State tax NOL sale	(3.8)%	(3.7)%
Nondeductible expenses	2.1%	(0.5)%
PPP loan forgiveness	(1.7)%	—%
Unrealized gain from termination of joint venture	(1.8)%	—%
Other	—%	(0.1)%
Change in valuation allowance for deferred tax assets	21.5%	31.6%
Income tax benefit	(4.7)%	(4.7) %

As of December 31, 2021 and 2020, the Company had accumulated net operating losses totaling $103.9 million and $87.2 million, respectively, in the U.S. (federal and state), which may be available to carry forward and offset future years' taxable income. U.S. federal losses can be carried forward indefinitely, and state losses expire in various amounts beginning in 2026. The Company also had accumulated losses totaling $3.6 million and $3.9 million in Germany which can be carried forward indefinitely.

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

During the year ended December 31, 2021 in accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused NOL carry forwards to other New Jersey based corporate taxpayers, the Company sold New Jersey NOL carry forwards, resulting in the recognition of $876,690 of income tax benefit, net of transaction costs. The Company recognized $1,170,890 of income tax benefit from the sale of New Jersey carry forwards in 2020. There can be no assurance as to the continuation or magnitude of this program in the future.

As of December 31, 2021, the Company had Federal and NJ research and development credits of $282,801 and $191,863 respectively. The Federal R&D credits can be carried forward 20 years and will begin to expire in 2038. The New Jersey R&D credits can be carried forward seven years and will begin to expire in 2025.

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, 2021, the Company does not have an accrual relating to uncertain tax positions. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. It is not anticipated that unrecognized tax benefits would significantly increase or decrease within 12 months of the reporting date.

Coronavirus Aid, Relief, and Economic Security Act

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, the "CARES Act", was enacted and signed into law, and GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date. The CARES Act, among other things, includes changes to the tax provisions that benefits business entities and makes certain technical corrections to the 2017 Tax Cuts and Jobs Act, including, permitting net operating losses, or NOLs, carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The CARES Act provides other reliefs and stimulus measures. The Company has evaluated the impact of the CARES Act, and determined that the provisions of the CARES Act did not have an impact on its financial statements or internal controls over financial reporting.

Note 16. Stock Based Compensation

On June 21, 2018, the Company adopted the 2018 Omnibus Equity Incentive Plan ("Plan"). This plan reserved 6.2 million shares with an increase to be added annually beginning in 2019 through 2028 up to 4% of the total number of shares of common stock issued and outstanding on a fully diluted basis as of the end of the immediately preceding fiscal year, providing that the aggregate number of additional shares shall not exceed a total of 45 million shares, and a maximum of 40 million shares pursuant to the exercise of stock options. Effective January 1, 2022, the number of shares reserved under the Plan was increased by 2.0 million to approximately 10.9 million. The Company's policy is to issue new shares of its common stock upon the exercise of stock options, new grants of restricted stock awards, and settlement of restricted stock units. Stock options issued under the plan have a contractual life of 10 years and are generally forfeited upon separation from the Company.

The following table presents stock compensation expense recognized by the Company for the years ended December 31, 2021 and 2020. Total unrecognized compensation cost related to equity awards as of December 31, 2021 was $4.3 million and is expected to be recognized over the next 2.0 years.

	Year ended December 31,	
	2021	2020
Selling, general and administrative	$ 2,901,624	$ 2,360,629
Research and development	332,503	831,944
Cost of goods sold	67,956	73,738
Total expense	$ 3,302,083	$ 3,266,311

The following table presents a summary of stock option award activity during the year ended December 31, 2021:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2021	3,815,585	$ 5.56	8.9	$ 342,551
Granted	1,355,136	1.97		$ 21,627
Exercised	—	—		$ —
Cancelled	(34,042)	5.53		$ 1,566
Outstanding, December 31, 2021	5,136,679	$ 4.61	8.0	$ —
Exercisable, December 31, 2021	2,356,657	$ 7.03	7.4	$ —

The intrinsic value is calculated as the difference between the fair market value at December 31, 2021 and the exercise price per share of the stock options. Options awards granted to employees generally vest over a four-year period.

The following table provides additional information about stock options that are outstanding and exercisable at December 31, 2021:

Exercise Price	Options Outstanding (number)	Options Outstanding Weighted Average Remaining Contractual Life (Years)	Options Exercisable (number)
$0.01 - $2.50	3,422,675	8.4	1,224,211
$2.51 - $7.52	677,250	8.1	243,018
$7.53 - $15.00	1,036,754	6.5	889,428

The following table presents a summary of restricted stock award ("RSA" or "RSAs") activity during the year ended December 31, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested, January 1, 2021	25,645	$ 10.07
Granted	165,413	2.41
Vested	(155,999)	2.88
Cancelled	(6,085)	5.45
Nonvested, December 31, 2021	28,974	$ 6.19

In general, RSAs granted to employees vest over a four-year period.

The following table presents a summary of restricted and deferred stock unit (“Unit” or "Units") activity during the year ended December 31, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested, January 1, 2021	1,014,123	$ 1.50
Granted	438,316	2.07
Vested	(391,410)	1.71
Cancelled	(5,354)	1.97
Nonvested, December 31, 2021	1,055,675	$ 1.66

In general, Units granted to employees vest over two to four years.

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

Valuation Information for Stock-Based Compensation

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

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

	2021	2020
Fair value at grant date	$ 1.32	$ 0.98
Expected volatility	80.2%	134.2%
Risk-free interest rate	0.7%	0.7%
Expected holding period, in years	6.0	6.1
Dividend yield	—	—

The fair value of RSAs and Units is the market close price of the Company’s common stock on the trading day immediately preceding the date of grant.

Note 17. Commitments and Contingencies

Stockholders Litigation

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

On February 21, 2020 the court granted the defendants' motion to dismiss the consolidated amended complaint with prejudice. On March 2, 2020 the court entered an amended order dismissing the consolidated amended complaint with prejudice. On March 27, 2020, the plaintiffs filed a notice of appeal with the N.J. Superior Court – Appellate Division. The appeal was argued on September 27, 2021. On October 8, 2021, the Appellate Division issued an order reversing the decision of the Superior Court. The case was remanded to the Superior Court for oral argument on the motion to dismiss. On November 11, 2021 the defendants filed a supplemental motion to dismiss based on the certificate of incorporation's forum selection clause. On December 10, 2021, the Superior Court heard argument of the original motion to dismiss and the supplemental motion to dismiss based on the federal forum selection clause. On December 14, 2021, the Superior Court granted both motions in their entirety and dismissed the action without leave to re-plead. On January 27, 2022, the plaintiffs filed a notice of appeal to the Appellate Division. A briefing schedule has been set by the Appellate Division for the appeal but an argument date has not been set.

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

In the *Turnofsky* case, on November 25, 2019 several plaintiffs and their counsel moved to be selected as lead plaintiff and lead plaintiff's counsel. On April 24, 2020. the Court granted the motion of Carole Tibbs and the firm Bragar, Eagel & Squire, P.C. On July 17, 2020 the plaintiffs filed an amended complaint in *Turnofsky*. In addition to the prior claims, the amended complaint added an additional director defendant and two investors as defendants and adds a claim against the Company and the underwriters for violating Section 12(a)(2) of the Securities Act. On September 15, 2020, the Company and the other defendants filed a motion to dismiss the amended complaint for failure to state a claim. On November 6, 2020, the plaintiffs filed their opposition to the motion to dismiss. The Company and the other defendants filed reply papers in support of the motion on December 7, 2020. Argument of the motion to dismiss occurred on June 18, 2021. On August 13, 2021, the Court dismissed the amended complaint with leave to re-plead. On October 4, 2021, the plaintiffs filed a second amended complaint. On November 17, 2021, the defendants moved to dismiss the new complaint. Briefing on the motion is now complete. Argument of the motion has not yet been scheduled.

The *Priewe* case was voluntarily dismissed on February 19, 2020.

On March 4, 2021, purported stockholder Richard Martz brought a purported stockholder derivative action in the United States District Court for the District of New Jersey. The action is captioned Richard Maltz, derivatively on behalf of electroCore, Inc., vs. Francis R. Amato, et al., Case 3:21-cv-04135. The defendants include present and past directors and officers of the Company. The plaintiff purports to pursue derivative claims on behalf of the Company in connection with the IPO and actions occurring between the IPO and September 25, 2019. The complaint alleges that demand on the board of directors is excused. The complaint purports to allege claims against the defendants for violating Section 14(a) of the Exchange Act, breaching fiduciary duties, unjust enrichment and waste of corporate assets. The complaint also purports to allege claims for contribution in connection with the Turnofsky case described above, pursuant to Section 11(f) of the Securities Act and Sections 10(b) and 21D of the Exchange Act. The complaint seeks unspecified compensatory damages, interest, costs and attorneys' fees; declaratory relief; and an order requiring changes to corporate governance and internal procedures and a vote on proposed amendments to the Bylaws and Certificate of Incorporation.

On March 8, 2021, purported stockholder Ewrin Yuson brought a purported stockholder derivative action in the United States District Court for the District of New Jersey. The action is captioned Erwin Yuson, derivatively on behalf of electroCore, Inc., vs. Francis R. Amato, et al., Case 3:21-cv-04481. The defendants include present and past directors and officers of the Company. The plaintiff purports to pursue derivative claims on behalf of the Company in connection with a 2019 proxy statement and actions occurring from the IPO through September 25, 2019. The complaint alleges that demand on the board of directors is excused. The complaint purports to allege claims against the defendants for violating Section 14(a) of the Exchange Act and breaching fiduciary duties. The complaint seeks unspecified compensatory damages, interest, costs and attorneys' fees; declaratory relief; and an order requiring changes to corporate governance and internal procedures and a vote on proposed amendments to the Bylaws and Certificate of Incorporation.

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

The Company expenses associated legal fees in the period they are incurred.

Purchase Commitments

The Company enters into contracts in the normal course of business with contract research organizations for its clinical trials, contract manufacturing organizations for the manufacture and supply of its clinical and commercial product needs and other vendors for other research and development and commercial activities, as well as services and products for operating purposes. The Company's agreements generally provide for termination with notice. Such agreements that are cancelable contracts are not included as purchase commitments. The Company has included as purchase obligations its commitments under agreements to the extent they are quantifiable and are not cancelable. The Company has purchase obligations of approximately $1.3 million as of December 31, 2021.

Note 18. Restructuring Charges and Other Related Charges

The following table provides a summary of the Company's restructuring and other related charges for the year end December 31, 2020:

	Year ended December 31, 2020
Employee separation costs	$ 271,164
Payment in lieu of severance	175,000
Other restructuring costs	18,442
	$ 464,606

In January 2020, the Company entered into a separation agreement with a former officer which agreement required an aggregate severance payment of $190,000 over a six-month period. In January 2020, the Company also entered into an agreement with a new employee that required the unconditional payment of $175,000, in lieu of future severance to be paid in equal monthly installments over a fourteen-month period. As of December 31, 2021, the Company has no payable in connection with the above described charges.

Exhibit 4.2

DESCRIPTION OF CAPITAL STOCK

The following description summarizes important terms of our capital stock. For a complete description, you should refer to our certificate of incorporation and bylaws, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, as well as the relevant portions of the DGCL.

General

As of the date of this Annual Report on Form 10-K, the Company has authorized 500 million shares of common stock, par value $0.001 per share. As of March 1, 2022, there were 70,718,191 shares of common stock outstanding.

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our certificate of incorporation and our bylaws, our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors are able to elect all of the directors standing for election, if they should so choose.

Dividend Rights

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are not entitled to receive ratably those dividends, if any, as may be declared from time to time by the Board out of legally available funds.

Liquidation Rights

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Other Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Anti-Takeover Provisions

The provisions of Delaware law, and our certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our Board. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to specified exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Our Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- ***Classified Board.*** Our certificate of incorporation provides for our Board to be divided into three classes with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding is able to elect all of our directors. Our certificate of incorporation and our bylaws also provide that directors may be removed by the stockholders only for cause upon the vote of 66 2/3% or more of our outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.
- ***Special Meetings of Stockholders and Stockholder Action by Written Consent.*** Our certificate of incorporation and bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminate the right of stockholders to act by written consent without a meeting. Our bylaws also provide that only our chairman of the board, Chief Executive Officer (or if there is no Chief Executive Officer, the President) or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.
- ***Advance Notice Requirements for Stockholder Proposals***. Our bylaws provide that stockholders seeking to present proposals before a meeting of stockholders, including the nomination of director candidates, must provide timely advance notice in writing, and specifies requirements as to the form and content of a stockholder's notice.
- ***Amendment to Certificate of Incorporation and Bylaws.*** Our certificate of incorporation and bylaws provide that the stockholders cannot amend the provisions described above except by a vote of 66 2/3% or more of our outstanding common stock.

The combination of these provisions makes it more difficult for our existing stockholders to replace our Board as well as for another party to obtain control of us by replacing our Board. Since our Board has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our Board to issue preferred stock with voting or other rights or preferences that could impede any attempt to effect a change of control of our company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our Board and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our certificate of incorporation provides that the Court of Chancery of the state of Delaware (the "Chancery Court") is the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty; (iii) any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; (iv) or any action asserting a claim against us that is governed by the internal affairs doctrine, in each case provided that the Chancery Court has subject matter jurisdiction. If the Chancery Court does not have subject matter jurisdiction, then such actions may be brought in any state court located in the state of Delaware (the "State Courts") or, if and only if the State Courts lack subject matter jurisdiction, in the federal district court for the District of Delaware.

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

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

In March 2020, the Delaware Supreme Court issued a decision in *Salzburg et al. v. Sciabacucchi*, which found that an exclusive forum provision similar to the one in our certificate of incorporation providing for claims under the Securities Act to be brought in federal court is facially valid under Delaware law. We intend to enforce the federal forum selection provision in our certificate of incorporation, but we do not know whether courts in other jurisdictions will agree with the *Sciabacucchi* decision or enforce it.

Limitation of Liability and Indemnification

Our certificate of incorporation provides that no director will be personally liable for monetary damages for breach of any fiduciary duty as a director, except with respect to liability:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL (governing distributions to stockholders); or
- for any transaction from which the director derived any improper personal benefit.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. The modification or repeal of this provision of our certificate of incorporation will not adversely affect any right or protection of a director existing at the time of such modification or repeal.

Our bylaws also provide that we will, to the fullest extent permitted by law, indemnify our directors and officers against all liabilities and expenses in any suit or proceeding or arising out of their status as an officer or director or their activities in these capacities. We will also indemnify any person who, at our request, is or was serving as a director, officer, employee, agent or trustee of another corporation or of a partnership, limited liability company, joint venture, trust or other enterprise. We may, by action of our Board, provide indemnification to our employees and agents within the same scope and effect as the foregoing indemnification of directors and officers.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc. 1717 Arch Street, Suite 1300, Philadelphia, Pennsylvania 19103.

Exhibit 10.3

RESTRICTED STOCK UNIT AGREEMENT
UNDER THE ELECTROCORE, INC.
2018 OMNIBUS EQUITY COMPENSATION PLAN

Pursuant to the electroCore, Inc. 2018 Omnibus Equity Compensation Plan (the "Plan"), electroCore, Inc., a Delaware corporation (together with all successors thereto, the "Company"), hereby enters into this Restricted Stock Unit Agreement with the undersigned employee (the "Grantee"), pursuant to which the Company will issue the number of shares of the Company's common stock equal to the number of Restricted Stock Units ("RSU's") granted hereunder in accordance with the terms set forth in this agreement (the "Agreement").

Notwithstanding anything in this Agreement to the contrary, the grant of the RSUs pursuant to this Agreement and the issuance of shares of the Company's common stock in settlement of such RSUs shall be subject to, and governed by, all the terms and conditions of the Plan. To the extent there is any inconsistency between the terms of the Plan and of this Agreement, the terms of the Plan shall control.

All capitalized terms used in this Agreement and not otherwise defined shall have the respective meanings given such terms in the Plan.

Number of RSUs Granted:
Grant Date:

1. **General.** Each RSU represents a right to receive one share of the Company's common stock (a "Share") in accordance with and subject to the terms and conditions of this Agreement and the Plan. By execution of this Award Agreement, the Grantee agrees to be bound by all of the terms and provisions of the Plan, the rules and regulations under the Plan adopted from time to time, and the decisions and determinations of the Committee made from time to time.

2. **Account for Grantee**. The Company shall maintain a bookkeeping account for the Grantee (the "Account") reflecting the number of RSUs then credited to the Grantee hereunder as a result of such grant of RSUs.

3. **Nontransferability.** The Grantee may not transfer RSUs or any rights hereunder to any third party other than by will or the laws of descent and distribution.

4. **Vesting and Forfeiture.** Subject to such further limitations as are provided in the Plan and as set forth herein, the RSUs shall vest and become exercisable on grant date of June 14, 2021

5. **Settlement - Delivery of Shares**. The Company shall issue the Shares underlying the portion of the RSUs granted hereunder that have vested pursuant to Section 4 to the Grantee (or to the Grantee's designated beneficiary if the Grantee has died) in settlement of the Grantee's vested RSUs as soon as reasonably practicable after the applicable Vesting Date.

6. **Withholding Taxes**. The Grantee agrees to make appropriate arrangements with the Company (or the appropriate Affiliate that employed the Grantee) for the satisfaction of all applicable Federal, state, local and foreign income and employment tax withholding requirements arising in connection with the vesting of the RSUs and issuance of Shares in settlement of such vested RSUs. The Grantee acknowledges and agrees that the Company may, refuse to deliver Shares if the Grantee does not deliver or make arrangements to deliver such required withholding amounts to the Company at the time the RSUs vest.

7. **Miscellaneous.**

(a) **Change and Modifications.** This Agreement may not be orally changed, modified or terminated, nor shall any oral waiver of any of its terms be effective. This Agreement may be changed, modified or terminated only by an agreement in writing signed by the Company and the Grantee.

(b) **Notices.** All notices, requests, consents and other communications shall be in writing and be deemed given when delivered personally, by telex or facsimile transmission or when received if mailed by first class registered or certified mail, postage prepaid. Notices to the Company or the Grantee shall be addressed as set forth underneath their signatures below, or to such other address or addresses as may have been furnished by such party in writing to the other.

(c) **Counterparts.** For the convenience of the parties and to facilitate execution, this Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same document.

[SIGNATURE PAGE FOLLOWS]

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned as of the date first above written.

ELECTROCORE, INC.

By:
Brian M. Posner
Chief Financial Officer

The undersigned hereby acknowledges receiving and reviewing a copy of the Plan and understands that the RSUs granted herein are subject to the terms of the Plan and of this Agreement. This Agreement is hereby accepted, and the terms and conditions thereof and of the Plan hereby agreed to, by the undersigned as of the date first above written.

GRANTEE:

Exhibit 10.4

NONQUALIFIED STOCK OPTION AGREEMENT
UNDER THE ELECTROCORE, INC.
2018 OMNIBUS EQUITY COMPENSATION PLAN

Name of Grantee:	(the "Grantee")
No. of Shares Underlying Options:	(the "Underlying Shares")
Grant Date:	(the "Grant Date")
Vesting Commencement Date:	"Vesting Commencement Date")
Expiration Date:	(the "Expiration Date")
Exercise Price/Share:	$ (the "Exercise Price")

Pursuant to the electroCore, Inc. 2018 Omnibus Equity Compensation Plan (the "Plan"), electroCore, Inc., a Delaware corporation (together with all successors thereto, the "Company"), hereby grants to the Grantee, an Option to purchase, on or prior to the Expiration Date (or such earlier date as provided in Section 3 below), all or any part of the number of Shares of Common Stock of the Company indicated above (the "Underlying Shares," with such Shares once issued being referred to herein as "Option Shares") at the Exercise Price per share indicated above.

Notwithstanding anything in this Nonqualified Stock Option Agreement (the "Agreement") to the contrary, this Option and any Option Shares acquired upon shall be subject to, and governed by, all the terms and conditions of the Plan. To the extent there is any inconsistency between the terms of the Plan and of this Agreement, the terms of the Plan shall control.

All capitalized terms used in this Agreement and not otherwise defined shall have the respective meanings given such terms in the Plan.

1. **Vesting and Exercisability**. Subject to such further limitations as are provided in the Plan and as set forth herein, the Option shall vest and become exercisable **as follows:**

(a) 1/3 of the Underlying Shares shall vest and become exercisable on the one-year anniversary of the Grant Date (the "One Year Anniversary"); and

(b) the balance of the Underlying Shares shall vest and become exercisable in two (2) equal annual installments over the succeeding 2 annual anniversaries of the One Year Anniversary, subject to the Grantee's continued employment with the Company and the terms and conditions of this Agreement and the Plan.

2. **Exercise of Option.** Prior to the Expiration Date (or such earlier date provided in Section 3 below), the Grantee may exercise this Option by delivering a Option exercise notice (an "Exercise Notice") in the form of Appendix A hereto indicating his or her election to purchase some or all of the Underlying Shares with respect to which this Option is vested and exercisable at the time of such notice and paying the Exercise Price for the number of Underlying Shares purchased. The Option may not be exercised for any fractional shares or any unvested shares.

3. **Termination of Affiliation.** Except as the Committee may otherwise expressly provide, or as may otherwise be expressly provided in any agreement between the Company and the Grantee, if the Grantee has a Termination of Affiliation with the Company and all of its Affiliates, the period within which the Grantee may exercise this Option may be subject to earlier termination as set forth below:

(a) **Termination of Affiliation Due to Death or Disability.** If the Grantee's Termination of Affiliation occurs by reason of such Grantee's death or Disability, this Option may be exercised, to the extent exercisable on the date of such termination, by the Grantee or by the Grantee's legal representative or legatee for a period of twelve (12) months from the date of such termination or until the Expiration Date, if earlier.

(b) **Termination for Cause.** If the Grantee has a Termination of Affiliation for Cause (as defined below), all Options (unvested and vested) shall terminate immediately**.**

(c) **Other Termination.** If the Grantee's Termination of Affiliation occurs for any reason other than death or Disability or Cause, this Option may be exercised, to the extent exercisable on the date of such termination, by the Grantee until the earlier of (i) the date that is three months from the date of the Grantee's Termination of Affiliation or (ii) the Expiration Date.

(d) **Treatment of Unvested Options on Termination of Affiliation.** Any portion of this Option that is not exercisable on the date of the Grantee's Termination of Affiliation for any reason shall terminate immediately and be null and void and of no further force and effect.

4. **Status of Option.** This Option is intended not to qualify as an "incentive stock option" as defined in Section 422(b) of the Internal Revenue Code of 1986, as amended.

5. **Disqualifying Dispositions**. Within 10 days after any Disqualifying Disposition (as defined in Section 6.4(f) of the Plan) of Option Shares acquired upon exercise of this Option, the Grantee shall notify the Company of such Disqualifying Disposition.

6. **Withholding Taxes**. The Grantee agrees to make appropriate arrangements with the Company (or the appropriate Affiliate that employed the Grantee) for the satisfaction of all applicable Federal, state, local and foreign income and employment tax withholding requirements, if any, arising in connection with the exercise of the Option. The Grantee acknowledges and agrees that the Company may refuse to honor the exercise and refuse to deliver Shares if the Grantee does not deliver or make arrangements to deliver such required withholding amounts to the Company at the time of exercise.

7. Miscellaneous Provisions.

(a) **Change and Modifications.** This Agreement may not be orally changed, modified or terminated, nor shall any oral waiver of any of its terms be effective. This Agreement may be changed, modified or terminated only by an agreement in writing signed by the Company and the Grantee.

(b) **Notices.** All notices, requests, consents and other communications shall be in writing and be deemed given when delivered personally, by telex or facsimile transmission or when received if mailed by first class registered or certified mail, postage prepaid. Notices to the Company or the Grantee shall be addressed as set forth underneath their signatures below, or to such other address or addresses as may have been furnished by such party in writing to the other.

(c) **Counterparts.** For the convenience of the parties and to facilitate execution, this Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same document.

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned as of the date first above written.

ELECTROCORE, INC.
By:
Brian Posner
Chief Financial Officer

The undersigned hereby acknowledges receiving and reviewing a copy of the Plan and understands that the Option granted hereby is subject to the terms of the Plan and of this Agreement. This Agreement is hereby accepted, and the terms and conditions thereof and of the Plan hereby agreed to, by the undersigned as of the date first above written.

GRANTEE:

DESIGNATION OF BENEFICIARY:_____

Appendix A
STOCK OPTION EXERCISE NOTICE

electroCore, Inc.
Attention: Corporate Secretary

_____
_____
_____

Pursuant to the terms of the stock option agreement between myself and electroCore, Inc. (the "Company") dated _____ (the "Agreement"), under the Company's 2018 Omnibus Equity Compensation Plan, I, [Insert Name] _____, hereby [Circle One] partially/fully exercise such Option by including herein payment in the amount of $_____ representing the purchase price for [Fill in number of Underlying Shares] _____ Option Shares. I have chosen the following form(s) of payment:

[ ] 1. Cash
[ ] 2. Personal, certified or bank check payable to **electroCore, Inc.**
[ ] 3. Wire transfer, or

through the sale of Option Shares through a broker-dealer to whom I have submitted an irrevocable notice of exercise and irrevocable instructions to deliver promptly to the Company the amount of sale proceeds sufficient to pay the exercise price for such Option Shares, together with the amount of applicable federal, state, local or foreign withholding taxes payable by me by reason of such exercise.

Sincerely yours,

_____
Name:

Address:

_____

_____

_____

ELECTROCORE, INC.

NON-EMPLOYEE DIRECTORS AMENDED COMPENSATION POLICY

This Policy (the "Policy") has been adopted by the Board of Directors ("Board") of electroCore, Inc. (the "Corporation") to document and memorialize the amount, timing and form of remuneration payable by the Corporation to its non-employee directors ("Non-Employee Directors") in consideration for their services to the Corporation. As hereby amended and restated, this Policy was adopted as of December 3, 2021 and shall become effective as of January 1, 2022 (the "Effective Date").

This Policy will remain in effect until this Policy is modified, replaced or terminated by the Board. The terms and conditions of any grant agreements entered into with Non-Employee Directors prior to the Effective Date shall remain in full force and effect without any change, including as to vesting and exercisability, and irrespective of the resumption of payment of cash compensation for Board service by Non-Employee Directors as set forth herein.

All capitalized terms used in this Policy and not otherwise defined shall have the respective meanings given such terms in the Corporation's 2018 Omnibus Equity Compensation Plan.

Section 1. Compensation. The Non-Employee Directors remuneration will include each of the following:

(a) **Cash Compensation**.

(i) Annual Retainer. Each Non-Employee Director will receive an annual retainer in an amount equal to $47,000 ($67,000 for the Board chair), payable in cash in equal quarterly installments on the 15th day of the second month of each calendar quarter (or the next business day if such day is not a business day, and each such date, a "Payment Date"), provided that the Non-Employee Director must continue to serve as a member of the Board through the applicable Payment Date to receive such quarterly installment payment.

(ii) Annual Committee Chair Retainer. The chair of each Board committee identified in the table below shall receive the annual committee chair retainer in the amount set forth opposite the name of such committee, payable in cash in equal quarterly installments on the Payment Dates commencing on or after the date such Non-Employee Director was appointed as the chair of such committee, provided that the Non-Employee Director must continue to serve as chair of such committee through the applicable Payment Date to receive such quarterly installment payment.

Committee:	**Annual Committee Chair Retainer:**
Audit:	$17,000
Compensation:	$11,000
Nominating & Governance:	$ 8,000

(b) **Annual Equity Awards**. Immediately following each year's annual meeting of the Corporation's stockholders, the Corporation will grant each Non-Employee Director an annual equity award valued at $75,000 ($112,500 for the Board chair) (an "Annual Equity Award") based on the closing price of the Corporation's common stock on the business day immediately preceding the grant date for such Annual Equity Award, provided that (i) each Annual Equity Award shall not exceed more than 75,000 shares (or 112,500 shares with respect to the Board chair), and (ii) in any calendar year, the Board shall have the discretion not to grant an Annual Equity Award to a Non-Employee Director who has joined the Board in such year and been awarded an Inaugural Equity Award (as defined below). Each Non-Employee Director may elect to receive his or her Annual Equity Award in the form of stock options, deferred stock units or restricted stock units. The Non-Employee Director must file his or her initial election with respect to the form of equity award with the Corporation before the later of the Effective Date or the date he or she becomes a Non-Employee Director. Thereafter, a Non-Employee Director may elect to change the form of equity award with respect to future Annual Equity Awards by filing a new election with the Corporation, which will become effective for calendar years following the year in which the Corporation receives such election. The Annual Equity Awards granted pursuant to this Section 1(b) will be subject to the terms and conditions (including vesting and settlement by issuance of shares of the Corporation's common stock) as shall be determined by the Board in its sole discretion.

(c) **One-Time Inaugural Equity Award**. Upon a Non-Employee Director's initial appointment or election to the Board after the Effective Date, the Corporation will grant such Non-Employee Director an inaugural equity award (an "Inaugural Equity Award") valued at $150,000 based on the closing price of the Corporation's common stock on the business day immediately preceding the date such equity award is granted provided that each Inaugural Equity Award shall not exceed 150,000 shares.

Each Non-Employee Director may elect to receive his or her Inaugural Equity Award in the form of stock options, deferred stock units or restricted stock units. The Non-Employee Director must file his or her election with respect to the form of equity award with the Corporation before the later of the Effective Date or the date he or she becomes a Non-Employee Director, as applicable. The Inaugural Equity Awards granted pursuant to this Section 1(c) will be subject to the terms and conditions (including vesting and settlement by issuance of shares of the Corporation's common stock) as shall be determined by the Board in its sole discretion; provided that unless otherwise provided by the Board, each Inaugural Equity Award will vest over a period of three years from the applicable grant date.

(d) **Exercisability after a Termination of Affiliation**. Annual Equity Awards and Inaugural Equity Awards granted to a Non-Employee Director in the form of options to purchase shares of the Corporation's common stock shall be exercisable from and after a Termination of Affiliation as follows:

(i) If a Termination of Affiliation occurs by reason of death or Disability of such Non-Employee Director, such options may be exercised, to the extent exercisable on the date of such termination, by the Non-Employee Director or their legal representative or legatee for a period of 12 months from the date of such Termination of Affiliation or until the applicable expiration date of the Annual Equity Award or Inaugural Equity Award, if earlier.

(ii) If a Termination of Affiliation occurs for any reason other than death or Disability of such Non-Employee Director, such options may be exercised, to the extent exercisable on the date of such termination, until the later of (x) 90 days after the date of such Termination of Affiliation and (y) the third anniversary of the applicable grant date; provided, however, that in no event shall such options be exercisable after the applicable expiration date of the Annual Equity Award or Inaugural Equity Award.

(e) **Change of Control**. In the event of a Change in Control, (i) all cash compensation payable to each Non-Employee Director pursuant to this Policy, including any and all such fees that would become due and payable during a calendar quarter in which the Change in Control occurs (as if the Non-Employee Director's service to the Corporation as a director had continued until the end of such quarter), shall be promptly paid to each Non-Employee Director no later than five days following the Change in Control and (ii) each unvested Annual Equity Award and Inaugural Equity Award then outstanding shall become fully vested upon the Change in Control.

(f) **Optional Deferred Settlement for Black-out Periods**. Notwithstanding anything to the contrary in this Policy, if the settlement date for any Annual Equity Award or Inaugural Equity Award made in the form of deferred stock units or restricted stock units would occur within any Black-out Period (as defined in the Corporation's Insider Trading Policy) applicable to the Non-Employee Director, then, upon the written election of the Non-Employee Director received by the Corporation prior to the original settlement date for such deferred stock units or restricted stock units, such shares will be issued in settlement of such units on the first business day following the expiration of such Black-out Period but not later than March 15 of the calendar year following the calendar year in which the restricted stock units become fully vested or December 31 of the calendar year in which the deferred stock units otherwise settle.

Section 2. Miscellaneous.

(a) **No Right to Continue as a Director**. Neither this Policy, nor the payment of any compensation hereunder, shall constitute or be evidence of any agreement or understanding, express or implied, that the Corporation will retain any participant as a member of the Board for any period of time.

(b) **Administration, Amendment and Termination**. This Policy shall be administered by the Board, whose construction and determinations shall be final. This Policy may be amended, modified or terminated by the Board at any time.

Exhibit 21.1

List of Subsidiaries of electroCore, Inc.

Subsidiary	Jurisdiction of Incorporation or Organization
electroCore Germany GmbH	Germany
electroCore UK Ltd.	United Kingdom

Exhibit 23.1

Independent Registered Public Accounting Firm's Consent

We consent to the incorporation by reference in the Registration Statement of electroCore, Inc. on Forms S-3 (No. 333-232655, 333-238721 and 333-262223) and Forms S-8 (No. 333-225864, 333-237498 and 333-254171) of our report dated March 10, 2022, with respect to our audits of the consolidated financial statements of electroCore, Inc. and Subsidiaries as of December 31, 2021 and 2020, and for each of the two years in the period ended December 31, 2021, which report is included in this Annual Report on Form 10-K of electroCore, Inc. for the year ended December 31, 2021.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 10, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel S. Goldberger, certify that:

1. I have reviewed this Annual Report on Form 10-K of electroCore, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Omitted pursuant to Exchange Act Rule 13a-14(a));

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

By: /s/ DANIEL S. GOLDBERGER

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian M. Posner, certify that:

1. I have reviewed this Annual Report on Form 10-K of electroCore, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Omitted pursuant to Exchange Act Rule 13a-14(a));

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

By: /s/ BRIAN M. POSNER

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of electroCore, Inc. (the "Company") on Form 10-K for the period ending December 31, 2021 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 results of operations of the Company.

Date: March 10, 2022

By: /s/ DANIEL S. GOLDBERGER

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of electroCore, Inc. (the "Company") on Form 10-K for the period ending December 31, 2021 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 results of operations of the Company.

Date: March 10, 2022

By: /s/ BRIAN M. POSNER

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