# 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, 2022**

**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 Capital 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 Capital Stock Market on June 30, 2022 was $33,125,433.

The number of shares of Registrant’s Common Stock outstanding as of March 1, 2023 was 4,742,450.

Portions of the Registrant’s Definitive Proxy Statement relating to the2022 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, 2022, 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.

- 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 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.
- We recently launched our Truvaga® and TAC-STIM® branded products for wellness and human performance. Commercialization of these products may be very expensive, time consuming and may not generate favorable financial results.
- Our business is subject to extensive governmental regulation that makes it expensive and time consuming for us to bring our gammaCore therapy and our general wellness products to market in the United States and other countries and to expand the use of our gammaCore therapy to additional therapeutic indications, and to expand the reach of our wellness initiatives.
- Risk associated with a failure to maintain regulatory approvals or clearances and other risk relating to the regulation of our industry and products including the conformity of our wellness products under FDA general wellness regulatory guidance.
- We depend heavily on revenue from the Department of Defense and the Department of Veterans Affairs for a substantial portion of our business. Changes in the U.S. Government's priorities, or delays or reductions in spending could have a material adverse effect on our business.
- Our potential revenue in the United Kingdom is substantially dependent on government funding arrangements and changes in governmental policy for such arrangements could cause material harm to our business.
- 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.
- If we fail to develop and retain an effective sales force, our business could suffer.

- 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 primary headache competitors are large, well-established companies with substantially greater resources than us and have a long history of competing in the migraine or wellness markets.
- Traditional therapy used to treat Cluster Headache (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 four 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 brands.
- The ongoing coronavirus pandemic could have a significant negative impact on our business, revenues, financial condition, results of operations and cash flow, and other epidemics or outbreaks of infectious diseases may have similar impact.
- 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 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, Truvaga, TAC-STIM 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

### Our Business

***An Overview***

We are a commercial stage bioelectronic medicine and wellness company dedicated to improving health through our non-invasive vagus nerve stimulation ("nVNS") technology platform. Our focus is the commercialization of medical devices for the management and treatment of certain medical conditions and consumer product offerings utilizing nVNS to promote general wellbeing and human performance in the United States and select overseas markets.

nVNS is a platform bioelectronic technology that modulates neurotransmitters through its effects on both the peripheral and central nervous systems. Our nVNS treatment is delivered through a proprietary high-frequency burst waveform that safely and comfortably passes through the skin and stimulates therapeutically relevant fibers in the vagus nerve. Various scientific publications suggest that nVNS works through several mechanistic pathways including the modulation of neurotransmitters.

Historically, vagus nerve stimulation or VNS, required an invasive surgical procedure to implant a costly medical device. This limitation has generally limited VNS from being used by anyone other than the most severe patients. Our medical devices and wellness products are self-administered and intended for regular or intermittent use over many years.

Our business is supported by our in-house capabilities spanning product development, regulatory affairs and compliance, sales and marketing, product testing, assembly, and fulfillment, and customer support. We derive revenues from the sale of medical devices and wellness products in the United States and select overseas markets. We have two principal product categories:

- Handheld, personal use medical devices for the management and treatment of certain medical conditions; and
- Handheld, personal use consumer product offerings utilizing nVNS technology to promote general wellbeing and human performance.

We believe our nVNS treatment may be used in the future to effectively treat additional medical conditions or improve human performance.

**Primary Marketed Products and Business Strategy**

Our goal is to be a leader in non-invasive neuromodulation by using our proprietary nVNS platform technology to deliver better health. To achieve this, we offer multiple propositions:

- gammaCore for the treatment of certain medical conditions such as primary headache;
- Truvaga for the support of general health and wellbeing; and
- TAC-STIM for human performance as defined by the United States Air Force Research Laboratory.

Our flagship model, gammaCore Sapphire, is a prescription medical device currently FDA cleared for a variety of primary headache conditions. gammaCore is available by prescription only and Sapphire is a portable, reusable, rechargeable and reloadable personal use option for patients to use at home or on the go. Prescriptions are written by a health care provider and dispensed from a specialty pharmacy, through the patient's healthcare system, or fulfilled directly to certain patients in the United States directly from our facility in Rockaway, NJ. After the initial prescription is filled, access to additional therapy can be refilled for certain of our gammaCore products periodically through the input of a prescription-only authorization.

Truvaga is a personal use consumer electronics wellness product that does not require a prescription and is available direct-to-consumer from electroCore at www.truvaga.com. Truvaga is not intended for medical use. TAC-STIM is a form of nVNS for human performance and has been developed in collaboration with the United States Department of Defense Biotech Optimized for Operational Solutions and Tactics, or BOOST program. We are exploring strategies to make this product offering available to other branches of the active-duty military and certain human performance professionals in the United States and abroad. TAC-STIM is available as a Commercial Off the Shelf (COtS) solution to professional organizations and is the subject of ongoing research within the United States Air Force Special Operations Command and at the United States Air Force Research Laboratory.

Truvaga and TAC-STIM are intended for general wellness in compliance with the FDA guidance document entitled "General Wellness: Policy for Low-Risk Devices; Guidance for Industry and FDA Staff, issued on September 27 2019". They are not intended to treat medical conditions.

We have generally focused most of our historical sales efforts in two channels, the United States Department of Veterans Affairs and United States Department of Defense, or VA/DOD, and the United Kingdom utilizing our FDA cleared and CE marked product, gammaCore.

The United States Department of Veteran Affairs comprised 60.8% of our revenue during the year ended December 31, 2022. We expect that a majority of our 2023 sales 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 the government channels. The FSS is scheduled to expire on January 15, 2024. We intend to request an extension of the FSS from the United States Department of Veterans Affairs, but there is no assurance the FSS agreement will be renewed, if at all, or at terms favorable to us, which could have an adverse impact on our financial results. Our sales function in this channel is comprised of employees and independent contractors.

Sales under the MTFM program for cluster headache in the UK comprised 15.1% of our revenue during the year ended December 31, 2022. In 2023, we plan on continued expansion under this program, as well as continue to utilize distribution partners to commercialize our nVNS technology in territories outside the United States and United Kingdom. In 2023, we expect the National Institute for Health and Care Excellence, or NICE, to review the guidance document and any changes in recommendation or pricing may adversely impact our ability to work with the National Health Service, or NHS, England on the MTFM program and could have an adverse impact on our financial results.

We believe there may be significant opportunities beyond these areas. In 2023, therefore, we plan to continue our investment in expanded commercial adoption of gammaCore with cash pay, physician dispense, and direct-to-consumer approaches, and continue our early efforts to begin building wellness and human performance propositions through Truvaga and TAC-STIM.

***Primary Headache Market and Competition for our gammaCore Products***

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 with most migraine patients managing their conditions with over-the-counter therapies. 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. There are many additional pharmaceutical approaches currently marketed and under development by third parties.

There are several neuromodulation devices that have been marketed for the treatment of migraine, including CEFALY (sold by CEFALY technologies sprl) 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.

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. 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. 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 episodic CH 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.

In the United Kingdom, the estimated prevalence of CH ranges from 0.1% to 0.2% of the total population, with approximately 66,000 affected patients.

Injectable sumatriptan (Imitrex) is an FDA-approved commercially available therapy for the acute treatment for CH. The side effect profile and cost of Imitrex, however, limits patients to treating only a small fraction of their attacks each month and has to be subcutaneously injected, which may be particularly difficult to do during an active 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 was recently approved by the FDA for the treatment of episodic CH. Additional medications that are used by patients off-label include verapamil, lithium, and valproate.

Our gammaCore therapy competes and will compete with numerous existing therapies from many different sources, including pharmaceutical, biotechnology, medical device and other healthcare companies, 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.

***Market and Competition for our General Wellness Products***

In April 2021, McKinsey & Company, or McKinsey estimated the global wellness market to be more than $1.5 trillion with annual growth of 5-10%, With the US market, spanning health, fitness, appearance, sleep, nutrition, and mindfulness, to be more than $450 billion and growing at great than 5% annually.

With the U.S. market, spanning health, fitness, appearance, sleep, nutrition, and mindfulness, estimated to be more than $450 billion and growing at greater than 5% annually. In a survey McKinsey conducted in August 2020 with roughly 7,500 customers in Brazil, China, Germany, Japan, the United Kingdom and the United States, 79% of the respondents said they believed wellness is important, and 42% considered it a top priority. Around 37% of surveyed consumers expressed a desire for additional products and services in both the sleep and mindfulness categories, with almost 1/3 of customers wanting more across the remaining four wellness dimensions.

***Research and Development***

We are developing future iterations of nVNS technology, including the use of our intellectual property around the delivery of smartphone-integrated and smartphone-connected non-invasive therapies.

We are supporting a variety of Investigator Initiated Trials (IIT) to evaluate additional indications and/or markets for our products. If successful, we believe these trials will provide marketing support for future expansion of our business to new indications and markets.

**Regulatory Clearances**

***Prescription***

gammaCore, which is our prescription only, handheld device intended for regular or intermittent use over many years, 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.

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 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. The FDA's Breakthrough Device designation is designed to expedite the development and regulatory review of medical devices that hold the potential for more effective treatment or diagnosis of life-threatening or irreversibly debilitating disease or condition.

We also are considering several additional medical indications for our nVNS technology which are being studied in several investigator-initiated trials, or IITs. These indications include, post-traumatic stress disorder, opioid use disorders, symptoms of Parkinson's disease, stroke, concussion, attention, nausea, mood, fatigue and memory retention among others.

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, NICE, published a Medical Technology Guidance document recommending the use of gammaCore for CH within NHS of England and Wales. We expect NICE to review the Medical Technology Guidance in 2023. 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. Effective April 1, 2021, gammaCore was listed on the NHS England MedTech Funding Mandate (MTFM) Policy. gammaCore is still listed in the policy, which requires commissioners fund the therapy from their existing allocations.

***Non-Prescription***

During 2022, we launched the Truvaga product line for consumer wellness applications.

During 2022, we launched the TAC-STIM product line designed for active-duty military personnel.

Truvaga and TAC-STIM are being marketed in the United States as wellness and human performance devices pursuant to the FDA guidance document entitled "General Wellness: Policy for Low-Risk Devices; Guidance for Industry and FDA Staff, issued on September 27 2019".

**Manufacturing**

We are the FDA-registered and ISO registered manufacturer of our nVNS products. We rely upon third-party contract manufacturers and suppliers, located both within and outside the United States, for substantially all the components of our nVNS products. In order to protect against risk of supply chain disruption, we seek to maintain adequate inventory and 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 what we consider to be 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. 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. We rely upon third parties, however, for the design function for new and modified devices.

At our facility in Rockaway, NJ, we inspect inbound component parts to ensure they meet our design and manufacturing specifications prior to assembly. This quality process involves physical inspection and electrical performance testing. After successful completion of this inspection, each unit is then assembled, packaged, along with appropriate labeling and accessories.

**Intellectual Property**

***Patents and Patent Applications***

As of February 1, 2023, we held more than 200 patents and patent applications, including 128 issued U.S. patents, 37 U.S. patent applications, and 45 international patents and applications. All of our current issued patents are projected to expire between 2026 and 2037.

***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, 2023, our trademark portfolio consisted of six US trademark registrations, including electroCore, gammaCore, and gammaCore Sapphire, 19 international trademark registrations, and 15 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.

***U.S. Food and Drug Administration (FDA) Regulation***

The majority of our products are medical devices that are subject to extensive regulation by the U.S. FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the regulations promulgated thereunder, as well as by other regulatory bodies in the United States and abroad. The FDA classifies medical devices into one of three classes based on the risks associated with the medical device and the controls deemed necessary to reasonably ensure the device's safety and effectiveness. Those three classes are:

- Class I, the lowest risk products, which require compliance with medical device general controls, including labeling, establishment registration, device product listing, adverse event reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations;
- Class II, comprising moderate-risk devices, which also require compliance with general controls and in some cases, so-called special controls that may include performance standards, particular labeling requirements, or post-market surveillance obligations; typically a Class II device also requires pre-market review and clearance by FDA of a pre-market notification (also referred to as a "510(k) application") as well as adherence to the quality system regulations/good manufacturing practices for devices; and
- Class III, high-risk devices that are often implantable or life-sustaining, which also require compliance with the medical device general controls and quality system regulations, but which generally must be approved by FDA before entering the market, through a more-lengthy pre-market approval (PMA) application. Approved PMAs can include post-approval conditions and post-market surveillance requirements, analogous to some of the special controls that may be imposed on Class II devices.

Before being introduced into the U.S. market, our medical devices must obtain marketing clearance or approval from FDA through the 510(k) pre-market notification process, the de novo classification process (summarized below under De Novo Classification Process), or the PMA process, unless they are determined to be Class I devices or to otherwise qualify for an exemption from one of these available forms of pre-market review and authorization by the FDA. To date, our products have all been classified as Class II, moderate-risk medical devices and have been subject to the 510(k) review and clearance process.

Additionally, the FDA also has a policy, *General Wellness: Policy for Low Risk Devices*, regarding general wellness products. Under this policy, the FDA does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FDCA or, if they are devices, whether they comply with the relevant regulatory requirements for devices (e.g., establishment registration, pre-market review). The policy defines general wellness products as products that meet the following two factors: (1) are intended for only general wellness use, as defined in the policy, and (2) present a low risk to the safety of users and other persons. We market Truvaga and TAC-STIM as general wellness products pursuant to this policy.

***510(k) Pre-Market Notification Process***

Class II devices typically require pre-market review and clearance by the FDA, which is accomplished through the submission of a 510(k) pre-market notification before the device may be marketed. To obtain 510(k) clearance, we must demonstrate that a new device is substantially equivalent to another device with 510(k) clearance or grandfathered status, or to a device that was reclassified from Class III to Class II or Class I - this device to which the new device is compared is called the "predicate device." In some cases, we may be required to perform clinical trials to support a claim of substantial equivalence. If clinical trials are required, we may be required to submit an application for an investigational device exemption, or IDE, which must be cleared by the FDA prior to the start of a clinical investigation, unless the device and clinical investigation are considered non-significant risk by the FDA or are exempt from the IDE requirements. Whether or not an IDE is required for a clinical study involving a medical device, an appropriate Institutional Review Board (IRB) must review and approve the study protocol before it is initiated. It generally takes three months from the date of the pre-market notification submission to obtain a final 510(k) clearance decision from the FDA, but it can be significantly longer.

After a medical device receives a 510(k) clearance letter, which authorizes commercial marketing of the new device for one or more specific indications for use, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires the submission of a new 510(k) notification or could require de novo classification or a PMA. The FDA allows each company to make this determination, but the FDA can review the decision as part of routine compliance audits of the company. If the FDA disagrees with a company's decision not to seek prior FDA authorization, the FDA may require the company to seek additional 510(k) clearance or pre-market approval. The FDA also can require the company to cease marketing and/or recall the medical device in question until its regulatory status is resolved.

***De Novo Classification Process***

If the FDA determines that a new, previously unclassified medical device or its intended use is not substantially equivalent to a predicate device, the device is automatically placed into Class III, requiring the submission of a PMA. Devices that cannot be cleared through the 510(k) process due to lack of a predicate device but would be considered low or moderate risk (in other words, they do not rise to the level of requiring the approval of a PMA because any risks associated with the device could be mitigated through general controls and/or special controls) may be eligible for the 510(k) De Novo classification process. If a product is classified as Class II through the De Novo classification process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications.

FDA has issued a Guidance document that formally codifies requirements for the medical device De Novo process and the procedures and criteria for product developers to file a De Novo classification request.

***PMA Application Process***

If a medical device does not qualify for the 510(k) pre-market notification process and is not eligible for classification as a low or moderate-risk device through the De Novo process, the device is deemed to be Class III and a company must submit a PMA application to seek authorization for its commercial sale. A PMA requires more extensive pre-filing testing than is required in the 510(k) application and is more costly, lengthy and uncertain. The PMA review and approval process can take one to three years or longer, from the time the PMA application is filed with the FDA. Under a PMA, the company must demonstrate to the FDA that the new medical device is safe and effective for its intended purpose. A PMA typically includes extensive pre-clinical and clinical trial data, and information about the device, its design, manufacture, labeling and components. Before approving a PMA, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the FDA's quality system regulation, or QSR.

If FDA approves the PMA, the approved indications may be more limited than those originally sought. In addition, FDA's approval order may include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution and post-market study requirements. Failure to comply with the post-approval conditions can result in adverse enforcement or administrative actions, including the withdrawal of the approval. Approval of a new PMA application or a PMA supplement may be required before making certain types of modifications to the device, including to its labeling, intended use or indication, or manufacturing process, especially when such modifications have the potential to affect safety and effectiveness.

***Post-Marketing Compliance Obligations***

Regardless of which pre-market pathway a medical device uses to reach the U.S. market, after a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other good manufacturing practice and quality assurance procedures during all aspects of the manufacturing process (unless a device category is exempt from this requirement by the FDA, such as in the case of many Class I devices);
- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other good manufacturing practice and quality assurance procedures during all aspects of the manufacturing process (unless a device category is exempt from this requirement by the FDA, such as in the case of many Class I devices);
- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other good manufacturing practice and quality assurance procedures during all aspects of the manufacturing process (unless a device category is exempt from this requirement by the FDA, such as in the case of many Class I devices);
- correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and device recalls or removals if undertaken to reduce a risk to health by the device or to remedy a violation of the FDA caused by the device that may present a risk to health;
- post-market surveillance regulations, which apply to Class II or III devices if the FDA has issued a post-market surveillance order and the failure of the device would be reasonably likely to have serious adverse health consequences, the device is expected to have significant use in the pediatric population, the device is intended to be implanted in the human body for more than one year, or the device is intended to be used to support or sustain life and to be used outside a user facility;
- regular and for-cause inspections by FDA to review a manufacturer's facility and its compliance with applicable FDA requirements; and
- the FDA's recall authority, whereby it can ask, or order, device manufacturers to recall from the market a product that is in violation of applicable laws and regulations.
- the guidance document entitled "General Wellness: Policy for Low Risk Devices; Guidance for Industry and FDA Staff, issued on September 27 2019" under which Truvaga and TAC-STIM are marketed under as wellness devices.

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 became applicable on May 26, 2021, with the transition period intended to end on May 26, 2024. While progress has been made on the transition from the MDD to the MDD, a European Commission proposal published on January 6, 2023, stated that the overall number and capacity of conformity assessment (a.k.a., ‘notified’) bodies remains insufficient to carry out the tasks required of them. In addition, many manufacturers are not sufficiently prepared to meet the strengthened requirements of the MDR by the end of the transition period. This is threatening the availability of medical devices on the EU market. According to an estimation presented by notified bodies to the Medical Device Coordination Group on November 17, 2022, the number of certificates issued by May 2024 may reach around 7,000 if the current rate of certificate issuance remains the same with no changes to current conditions. Notified bodies estimate that the transition of all Directives’ certificates to MDR certificates could possibly be completed by December 2027. The European Commission’s “Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, Brussels, 1.6.2023 intends” to extend the transition period from May 26, 2024 until December 31, 2027 for high-risk Class III and Class IIb implantable devices, and until December 31, 2028 for medium and lower risk Class IIb and Class IIa devices. The gammaCore products (gammaCore Sapphire, gammaCore-S) are EU Class IIa devices. 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.

***Federal Trade Commission***

We are subject to Federal Trade Commission, or FTC, regulatory oversight. Under the Federal Trade Commission Act (FTC Act), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, or injunctions affecting the manner in which Truvaga could be marketed in the future.

***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.

*Advertising and Promotion*

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the FTC and by federal and state regulatory and enforcement authorities, including the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and various state attorneys general. Although physicians are permitted to use their medical judgment to use medical devices for indications other than those cleared or approved by the FDA, we may not promote our products for such "off-label" uses and can only market our products for cleared or approved uses. Other companies' promotional activities for their FDA-regulated products have been the subject of FTC enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. FTC enforcement actions often result in consent decrees that constrain future actions. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

*Import and Export Requirements*

To import a device, the importer must file an entry notice and bond with the United States Bureau of Customs and Border Protection (CBP). All devices are subject to FDA examination before release from CBP. Any article that appears to be in violation of the FDCA may be refused admission and a notice of detention and hearing may be issued. If the FDA ultimately refuses admission, the CBP may issue a notice for redelivery and, if a company fails to redeliver the goods or otherwise satisfy CBP and the FDA with respect to their disposition, may assess liquidated damages for up to three times the value of the lot. The CBP also imposes its own regulatory requirements on the import of our products, including inspection and possible sanctions for noncompliance.

***Human Capital Resources***

As of March 1, 2023, we employed 62 full-time employees in the US and abroad 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. New employees are provided industry-relevant compliance training and are introduced to our Code of Business Conduct and Ethics to which all employees are required to annually confirm compliance.

Employee health and safety in the workplace is one of our core values. The ongoing 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. For example, since the advent of the pandemic in the first half of 2020, the majority of our employees previously based in our then headquarters in Basking Ridge, NJ have generally conducted business remotely, which has allowed us to reduce our real estate space requirements.

***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 UK Ltd. and electroCore Germany GmbH. 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. We also maintain websites at www.gammacore.com, www.gammacore.co.uk, and www.truvaga.com. The content reflected on our websites are 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 Annual Report, including the section of this Annual 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 Annual Report occur, our business, operating results, and financial condition could be seriously harmed. This Annual Report 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 Annual Report.*

### 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, as well as our direct-to-consumer business channel and patients and providers or consumers may be slow to adopt these programs or their pricing which could adversely impact our business and financial results.***

We currently have a cash-pay business channel for our gConcierge and gCDirect programs, and intend to expand our direct-to-consumer business channel through the recently launched ecommerce websites by increasing our advertising and promotional activities in 2023. This will require significant investment and expansion of our sales and marketing capabilities and further development by us 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 our direct-to consumer business channel and do not achieve the sales levels that we reasonably anticipate to materialize in light of current planning and forecasting, we will be unable to recover the investments described above. 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, this risk could have an adverse impact on our financial position and results of operations as well as heighten our need to obtain additional financial capital to support our business projects.

***If third-party payors 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 payor organizations provide adequate coverage and reimbursement for the cost of our products. Many third-party payors do not currently cover nVNS for any indications other than epilepsy because they have determined all other nVNS 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 data observed in our existing clinical studies, and we cannot provide similar assurance that our current or future published clinical evidence will be sufficient to obtain adequate coverage and reimbursement for gammaCore. Moreover, if we cannot obtain adequate coverage for and reimbursement of the cost of gammaCore, we cannot provide assurance that patients will be willing to incur the full cost of our gammaCore therapy. Access to adequate coverage and reimbursement by third-party payors for our gammaCore therapy or the willingness of patients to bear the entire cost of our therapy is essential in the acceptance of our gammaCore by physicians, patients, and other customers for our therapy.

Third-party payors, 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 payors. Therefore, coverage and reimbursement for our gammaCore therapy can differ significantly from payor to payor. In addition, payors 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 payor 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 and government-managed systems. If sufficient and timely coverage and reimbursement are not available for our current or future gammaCore products, or if reimbursement rates change, in either the United States or internationally, the demand for our gammaCore product and our revenues would be adversely affected.

***We have a limited history commercializing our VNS platform technology, including through direct-to-consumer channels, and commercial success is uncertain.***

Moreover, 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 are becoming increasingly important to direct-to-consumer initiatives. We may be unable to gain broader market acceptance for our nVNS platform technology in our sales channels and markets, including direct-to-consumer channels 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 our own products and 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;
- limited brand awareness
- 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 in relevant geographic and product markets.

***We have a limited history commercializing our wellness and human performanceproducts in the United States for which market acceptance and commercial success are uncertain.***

As a small company with a limited history of selling our wellness and human performance products, we have limited experience engaging in commercial activities and limited established relationships and experience with direct-to-consumer channels and third-party suppliers on whom we depend for the manufacture of our product components. In addition, as a general matter, we may fail to adapt our existing or future technology to patient and customer requirements or emerging treatment standards in our relevant geographic and product markets. New industry standards for the development, manufacture, and marketing of medical devices and general wellness products may evolve in separate ways, and we may not be able to conform to the changes, meet new standards in a timely fashion, or maintain a competitive position in our target marketplace. Moreover, if we face material delays in introducing our products and new technology, we may fail to attract new customers in part due to diminished brand awareness and ineffective implementation of marketing and promotion strategy. Specifically, we may be unable to successfully commercialize our wellness and human performance products in the United States for a number of reasons, including:

- established competitors with relatively more mature relationships with their customers and third-party suppliers;
- limitations in our ability to demonstrate differentiation and advantages of our product compared to similar, competing products and the relative safety, efficacy and ease of use of our product;
- the limited brand awareness of our Truvaga and TAC-STIM brands, which are our two recently launched non-prescription, wellness and human performance products;
- the limited size of our marketing budget to assess and increase customer demand levels;
- the inability to obtain sufficient supply of the product components for our wellness products from our primary and secondary manufacturers and suppliers;
- insufficient financial or other resources to support our commercialization efforts necessary to realize profitability; and
- the introduction, and market acceptance, of new, relatively more effective, or less expensive, competing products and technologies.

***We recently launched our Truvaga and TAC-STIM branded products for wellness and human performance. Commercialization of these products may be very expensive, time consuming and may not generate favorable financial results.***

We recently launched our business for wellness and human performance for our Truvaga and TAC-STIM branded products. We have limited experience in this area and our initiatives may require significant investment to develop our sales and marketing capabilities for this business channel. If we are unsuccessful in executing our commercialization efforts in this business channel and do not achieve the sales levels that we expect at all or within the time frames we have forecast, we may need to obtain additional financing on terms that may be dilutive or disadvantageous and we may be unable to recover these investments.

***We have limited operating experience at our current scale of operations. If we are unable to manage our growth effectively, our brand, company culture, and financial performance may suffer.***

Implementation of our growth strategy for our gammaCore and human performance and wellness products may require greater overall planned capital expenditures, and we cannot guarantee that any such increased expenditures will bring forth corresponding, offsetting revenue growth. Because we have a relatively limited history operating our business at its current and evolving scale, it is difficult for us to evaluate our present and future business prospects, including our ability to plan for, and model, future growth scenarios. Our limited operating experience at this scale, combined with the rapidly evolving customer demand and other market structure properties of the health and wellness geographic and product markets in which we operate and other economic factors beyond our control, reduces our ability to accurately forecast quarterly or annual revenue. In particular, our ability to accurately forecast customer demand could be affected by myriad factors, including, without limitation, changes in customer demand levels for our products, changes in demand levels for the products of our competitors, the relative pace of acceptance of personalized health and wellness recommendations, unanticipated weakening of various macroeconomic conditions, and capricious shifts in consumer confidence in future macroeconomic stability and/or the public capital markets. Failure to manage our future growth plans effectively could have an adverse effect on our financial condition and operating results.

***Any significant disruption to our ecommerce business could result in lost sales.***

In early 2022, we launched new cash pay initiatives for our gammaCore therapy, including our ecommerce 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, harming our brands. Operating our direct-to-consumer ecommerce business depends on our ability to maintain the efficient and uninterrupted administration of online prescription generation, order-taking, and fulfillment activities. 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 and efficacy 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 pressures in wages in local and regional labor markets; structural labor market benefits, whether driven by competition for talent or ordinary course pay increases, and 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 adversely impact our results of operations and financial condition if we are not able to pass those costs on to our patients and consumers or charge premium prices when justified by actual or perceived market demand.

Moreover, some of our existing or future customers may consider our products and services to be discretionary by nature. Factors affecting the aggregate level of spending for such customers possibly include current macroeconomic conditions, including inflation, consumer confidence in future macroeconomic conditions, fears of recession, the availability and cost of customer credit, rates of employment, and tax rates, which are factors that would adversely impact demand for our products.

***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 as well as your investment.***

We have experienced significant net losses, and we expect to continue to incur losses for the foreseeable future while we operate our sales and marketing infrastructure, endeavor to increase acceptance of our gammaCore therapy and launch our human performance and wellness product line in relevant markets, fund our various 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 $22.2 million and $17.2 million for the year ended December 31, 2022 and 2021, respectively. As of December 31, 2022, our accumulated deficit was $146.4 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 nVNS platform technology and identify promising areas of adoption with significant potential in terms of marketability, brand awareness, and product distinguishability, among other business considerations. This will require us to be successful in a range of challenging activities, which may include obtaining adequate coverage and reimbursement from payors; marketing and selling any current and future product candidates for which we may obtain appropriate marketing clearance, approval or authorization; developing commercial-scale manufacturing processes; managing various risks associated with the design, manufacture, marketing, and sale of human performance, wellness product offerings, including compliance risk stemming from inadequate monitoring and analysis of applicable FDA and other relevant guidance as well as applicable consumer protection laws, rules, and regulations, ineffective initial and periodic assessment of claims and intended uses of such offerings, and inadequate government affairs, regulatory change management, or other corporate compliance functions that typically identify and remediate nonconformance with administrative law requirements, whether U.S. federal, state, or otherwise, and execute regulatory compliance processes more broadly; completing future clinical trials of gammaCore for additional therapeutic indications; obtaining additional marketing clearance, approval, or authorization from applicable regulatory authorities; militating against risk in, and enhancing the measures of cost efficiency in, our manufacturing; satisfying any post-marketing requirements; and developing the marketing and promotional expertise necessary to succeed in an integrative, well-funded direct-to-consumer approach through the sale of our wellness and human performance product offerings. Because of the numerous risks and uncertainties associated with our commercialization efforts as well as our 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 our nVNS platform technology. We intend to continue to make targeted investments in building our U.S. and UK commercial infrastructure.

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 may be forced to further reduce, or ultimately terminate, our operations. As of December 31, 2022, we had cash and cash equivalents and marketable securities of $18.0 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 and 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, and expand our business or continue our operations. Accordingly, a decline in the market value of our company 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 2023 and beyond. This will require significant investment in, and expansion of, our sales and marketing capabilities and use of our own ecommerce platform, as stated previously. If we are unsuccessful in executing our commercialization efforts in this business channel and do not achieve the sales levels that we expect in light of our current plans and forecasts, we may be unable to recover these investments. Additionally, there is a risk that expanding our direct-to-consumer cash-pay business channel could erode demand for our prescription products, depress pricing with third-party payors 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 consistent with servicing our existing, new, and evolving sales channels, including direct-to-consumer are critical to our sales strategy. The market for qualified professionals is evolving, dynamic, and increasingly challenging. Our corporate reputation is a significant factor on consumers' evaluation of whether to buy our products and on 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 would 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 higher costs and price increases that could in turn lead to a general reduction in demand levels 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 relating 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.

***Our consultants and certain of our sales force are classified as independent contractors, and we can face consequences if it is determined that they are misclassified as such.***

There is often uncertainty in the application of worker classification laws, and, consequently, there is risk that our independent contractors could be deemed to be misclassified under applicable law. The tests governing whether a service provider is an independent contractor or an employee are typically highly fact-intensive and vary by jurisdiction. Laws and regulations that govern the status and misclassification of independent contractors are also subject to divergent interpretations by various authorities, which contributes to uncertainty or unpredictability in the law. A misclassification determination or allegation creates potential exposure for us, including, but not limited to, monetary exposure arising from or relating to failure to withhold and remit taxes, unpaid wages, and wage and hour laws and requirements (such as those pertaining to minimum wage and overtime); claims for employee benefits, social security, workers' compensation and unemployment; claims of discrimination, harassment, and retaliation under civil rights laws; claims under laws pertaining to unionizing, collective bargaining, and other concerted activity; and other claims, charges, or other proceedings under laws and regulations applicable to employers and employees, including risks relating to allegations of joint employer liability. Such claims could result in monetary damages (including, but not limited to, wage-based damages or restitution, compensatory damages, liquidated damages, and punitive damages), interest, fines, penalties, costs, fees (including, but not limited to, attorneys' fees), criminal and other liability, assessment, or settlement. Such an allegation, claim, adverse determination, including but not limited to with respect to advisors and consultants that provide services to us, could also harm our brand and reputation, which could in turn adversely impact our business.

***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, and financial condition.***

We anticipate that we will experience price fluctuations for our products due to pricing pressure relating to our efforts to increase consumer demand for our products. We may also face pricing pressure from managed care organizations and other third-party payors due to increased market power of our payors while the medical device industry consolidates as well as 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, could be adversely affected. Macroeconomic conditions may result in increased costs for manufacturing and outsourced services and cause 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 ongoing COVID-19 pandemic and its effects and macro-economic conditions could have on our business operations and financial condition. Any increased or unexpected pricing pressures, costs, delays, or failures to achieve cost savings, and 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 and 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;
- various challenges with regard to the acquired company's products and technology in the existing internal corporate and customer facing systems or processes;
- integration of the acquired company's accounting, management information, human resources, and other administrative systems or processes;
- the need to implement or improve controls, procedures, and policies in a preexisting business organization 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 VNS platform technology, and to opportunistically pursue research and development activities for additional indications for our gammaCore therapy. There is no assurance that we will have sufficient cash flow and liquidity to fund our planned activities. 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. There is no assurance that we will generate sufficient funds through our operating results or financing activity thereby raising substantial doubt about our ability to continue as a going concern within one year of the date the financial statements included in this Annual Report. Changes, including those relating to the payor 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 payor 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 payor, physician, patient, and market acceptance of our gammaCore therapy;
- the degree and rate of consumer adoption of our non-prescription, wellness product offerings;
- 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 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 payors and service providers, to potentially implement new or revised policies, infrastructure, and internal systems;
- our ability to hire additional personnel to support our various functions and 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 or private 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 macroeconomic factors may affect our ability to raise funds and the terms on which we will be able to raise funds. Our failure to obtain additional necessary financing could impair our ability to conduct our operations, and any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to (i) pursue our business plans and strategies and (ii) maintain our listing on the Nasdaq Stock Market.

In addition, our auditors report for our 2022 financial statements contains a statement concerning our ability to continue as a "going concern". Our lack of sufficient liquidity could make it more difficult for us to secure additional financing terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our stock price generally. Our 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, strategic transactions, or otherwise. However, there are significant risks and uncertainties as to our ability to achieve these goals or to obtain required funding on commercially reasonable terms or at all, including as a result of the adverse impact on our business from the ongoing COVID-19 pandemic and other macro-economic conditions. 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 and we may be unable to compete effectively, and the growth of our business would be materially and adversely harmed.

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

***Regulatory requirements and changes to payors' 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 payor 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 payors 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 of gammaCore 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 payors 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 may involve higher credit risks than sales to other payors.

Revenues from the sale of our gammaCore therapy partially 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 payors whose payment of claims may be contingent upon the payment of another payor. Because of the coordination with multiple payors, 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 the 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 payors 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 payors' pharmacy benefit has not achieved adequate coverage and reimbursement. To obtain coverage and reimbursement from Medicare and any other third-party payor 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 payors 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 are 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 payors to not cover gammaCore under the pharmacy benefit pathway. Coverage by commercial payors through the medical benefit pathway or other decisions by commercial payors 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 payors 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 payors 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., and Pfizer 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 compared to existing traditional treatments for cluster and migraine headaches.

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 relative 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 do 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 and adversely affected.

***We must demonstrate to customers the benefits of nVNS platform technology for general wellbeing and human performance compared to those of our competitors and such comparisons may not be realizable.***

Consumer sentiments play a significant, and increasing, role in determining customer adoption of certain wellness products. In general, our success depends on the continued willingness of consumers to use health and wellness products and services and to place value in the primacy of scientific evidence in the marketing of wellness products and services. To be successful, we will need to continue to significantly invest in educating consumers about our products. This need is elevated in the light of the health and wellness market's particular characteristics. The market is heavily saturated, and the expected future demand for and market acceptance of innovative products and services in the market are uncertain. While we believe it is reasonable to predict that the overall health and wellness market will continue to grow, it is difficult to predict the future growth rates, if any, of certain sectors that intersect with comparable and substitution products relevant to our business. As a result, if our market does not further develop, or develops more slowly than expected, or becomes saturated with competitors with greater financial or other resources, or if our products do not achieve sufficient adoption in accordance with present and future business plans, our financial condition, and operating results could be materially and adversely affected. In particular, as stated previously, acceptance of our nVNS platform technology depends on educating patients as to the distinctive characteristics, perceived benefits, safety, ease of use, and cost-effectiveness of our nVNS platform technology relative to our competitors' products and communicating to customers the proper use of our nVNS products. As a result, our success depends, in large part, on effectively marketing our nVNS platform technology to consumers. For our nVNS platform technology to gain widespread adoption, we must successfully demonstrate to consumers the relative benefits of our nVNS platform technology compared to competitors' products. We also may face challenges because nVNS is relatively new compared to existing wellness products across a multitude of price points. Further, the competitive landscape for wellness products is crowded and continues to rapidly evolve. Therefore, our wellness business line faces a diverse set of challenges that may have a significant effect on your investment.

***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 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 gammaCore products 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 gammaCore products. Because our platform is novel, regulatory agencies, as well as insurance and other coverage providers and payors, 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 gammaCore and 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 payor acceptance of our gammaCore therapy;
- patients' acceptance of our nVNS platform technology gammaCore therapy;
- customer acceptance of our wellness and performance products;
- payor adoption;
- estimated useful life of products;
- the timing of when individual payor 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 payors’ 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 introduce additional risk into our business because we may rely upon forecasts of customer demand to build inventory in advance of anticipated sales. In addition, we believe our limited commercial history 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, 2022 and 2021, revenue from Department of Veteran Affairs and Department of Defense (VA/DoD) facilities pursuant to the terms and conditions of our qualifying contract under the Federal Supply Schedule and open market sales represented 60.8%and 59.8% of our total revenue, respectively. In 2022, five specific VA/DoD facilities represented approximately 52.8% of our revenue from this channel, and one of those facilities 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.

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 that subject us to other risks.***

We may evaluate various strategic transactions, including licensing or acquiring complementary therapies, products and 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 entity or 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, and technologies. Accordingly, from time to time, we may consider opportunities to acquire or make investments in businesses, or make investments in or license other technologies and products, that may enhance our capabilities, complement our current products, or expand the geographic or product 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 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 and 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 are 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 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. We have recently reduced resources in research and development which may delay our receipt of regulatory approvals for additional indications. 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, will 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 non-compliance 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.

Consistent with recent years, we continue not to invest in certain clinical trials in indications that are more exploratory in nature.

We could also encounter delays if a clinical trial is suspended or 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 result 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 could 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 obtain 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 continue to grow our existing business 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, or 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 nVNS platform technology, 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. 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, in the past, we have been subject to, and may, in the future, be subject to, 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 limited history of commercializing wellness products withing the United States or abroad. We have limited established relationships with stakeholders and experience in direct-to-consumer channels and limited relationships with third-party suppliers on whom we depend for the manufacture of our product components.

***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 primary headache competitors are large, well-established companies with substantially greater resources than us and have a long history of competing in the migraine or wellness markets.***

Many of our current and potential primary headache 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., Pfizer 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 share of the market.

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 would be adversely affected.

In the United Kingdom, three of the CGRP monoclonal antibody therapies have been recommended for use in the National Health Service by the National Institute Health and Care Excellence for the prevention of migraine. All of our current business with the National Health Service in the United Kingdom is for the prevention and treatment of cluster headache, and these recommendations may limit our ability to penetrate the NHS migraine market in the United Kingdom.

Furthermore, 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, payors, 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.

Given our nascent entry into the diverse human performance and wellness market, we expect that the barriers of entry and competitive effects may be significant factors impacting our success in the research and development, advertising, marketing, promotion, distribution, and sale of our general wellness products, Truvaga and TAC-STIM, respectively. We expect to continue to perform, or engage with consultants to perform, where appropriate, extensive market research and other economic analysis to appropriately understand market participants' product offerings and contextualize various empirical and conjectural properties of market structure, including pricing patterns, competitive or anticompetitive tendencies, collaborative ventures and synergies, and cross-market product substitutions and other consumer behavior inferences, among other factors. To effectively compete with more established marker participants in the wellness industry, we may need to expand our product offerings and distribution channels, which, in the interim, could increase our research and development costs and decrease our operating margins, thereby adversely impacting our business, financial condition, and results of operations. Some of the world's largest technology companies that have not historically operated in the wellness and/or medical device spaces, such as Alphabet Inc., Amazon.com, Inc., Apple Inc., Samsung Electronics Co., Ltd., and others have notably developed or may in the future develop products and technologies that may compete with our current or future products and technologies. Such companies have substantially greater capital, research and development, and sales resources than we have. Future research or investigative reports or publicity that is perceived as unfavorable or that question certain claims associated with or methods underlying our general wellness products could result in a decline in our revenues. Because of our final dependence on consumer perceptions, adverse publicity associated with illness or other undesirable effects resulting from the use of our products or similar products by competitors, whether or not accurate, could also damage customer confidence in our existing and any future general wellness products and result in a decline in revenues. Adverse publicity could arise even if the unfavorable effects associated with our general wellness products resulted from the user's failure to use such products appropriately.

***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 four 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. In addition, 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 and 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 represent 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 and the purchase of components from international sources subjects us to U.S. 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 of 1977 (or FCPA), as amended, and export controls laws. The failure to comply with U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions could materially adversely affect our business and result in civil and/or criminal sanctions.

With regard to FCPA, the UK Bribery Act, and similar worldwide anti-bribery laws in non-U.S. jurisdictions, such laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials and, in some instances, other persons for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the United States are or will be with governmental entities and are therefore potentially subject to such anti-bribery laws. Notably, global enforcement of anti-corruption and anti-bribery laws, which are typically interpreted broadly to prohibit generally companies, their employees, and their third-party intermediaries from authorizing, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector, has increased substantially in recent years, which has in part led to more frequent voluntary self-disclosures by companies, aggressive investigations and enforcement proceedings by U.S. and foreign governmental agencies, and assessment of significant fines and penalties against companies and individuals in various cases.

Thus, our international operations create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors because these parties are not always subject to our direct oversight and control. As we increase our international sales and direct greater levels of business and sales toward the public sector, we may engage with business partners and third-party intermediaries to market our products and to obtain necessary permits, licenses, and other regulatory approvals. In addition, we or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. **[**It is therefore our policy to implement safeguards to educate our employees and agents on these legal requirements and discourage improper practices.**]** However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, contractors or consultants, partners, sales agents, or distributors may engage in conduct for which we might be held ultimately responsible as principal. Specifically, we can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors or consultants, partners, and sales agents, or distributors, even if we do not explicitly authorize such activities. Detecting, investigating, and resolving actual or alleged violations of anti-corruption and other laws can require a significant diversion of time, resources, and attention from our business.

In addition, government agencies may seek to hold us liable for successor liability for anti-corruption law violations committed by any companies in which we invest or that we acquire in the future. Any alleged or actual violations of these regulations may subject us to expensive government scrutiny, severe criminal or civil sanctions and other liabilities, including exclusion from government contracting, reputational harm, adverse media coverage, and such alleged or actual violations could disrupt our business and result in a material adverse effect on our business, financial condition, and results of operations. As we expand contract relations internationally, our risks under these laws may increase.

In general, any failure to comply with the 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 U.S. 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 ongoing 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 firms 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. Our general costs of doing business 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 and indirect effects from net capital flows related risks, such as capital flight and any cross-border capital controls. 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 brands.***

We believe that establishing and strengthening the electroCore, gammaCore, Truvaga, and TAC-STIM brands are critical to achieving widespread acceptance of our nVNS platform technology. We believe that brand awareness considerations are particularly significant in light of the highly competitive nature of the burgeoning markets for headache therapies and wellness products. 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 relative 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 brands. If we fail to successfully promote, expand, and maintain our brands, or if we incur substantial expenses in an unsuccessful attempt to promote, expand, and maintain our brands, nVNS platform technology 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 our nVNS platform technology 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. Regardless of the merits or eventual outcome, liability claims may result in any of the following:

- decreased demand for our products or products that we may develop in the future;
- decline in price charged for our products;
- loss of revenue;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls or withdrawals;
- labeling, packaging, marketing or promotional modifications or restrictions;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our existing or future products; and
- a decline in our stock price.

Although we have, and intend to maintain, liability insurance, the insurers may deny our claims, and coverage limits of our insurance policies may not be adequate. Specifically, we may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations, or that are not covered by the terms and conditions of our insurance policies, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. These risks are particularly heightened in the event any product recalls take place as a result of any product design defect or defect in product warnings or labeling. One or more successful claims brought against us may have a material adverse effect on our business and results of operations. Even successful defense would require significant financial and management resources.

***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 accounts receivable, and inventory. Significant management judgment must be used, and estimates must be made in relation to establishing the foregoing reserves, and any increase thereto could adversely affect our reported financial results by reducing our net revenues and/or profitability for the given reporting period.
If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, or if third-party payors were to deny claims, additional provisions for doubtful accounts may be required.

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

Additionally, damaged or defective products could (i) adversely affect our reputation and our end customers' willingness to buy products from us, (ii) adversely affect market acceptance or perception of our products, (iii) increase our service costs, (iv) cause us to lose significant end-customers, and (v) subject us to liability for damages and divert our resources from other tasks, any of which could materially and adversely affect our business, 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 militate against 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. This 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 while 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 transition to 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. Possible misconduct by these parties, including intentional, reckless, or negligent conduct or otherwise unauthorized activities, that violates the (1) 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, advertising and 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, advertising, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Misconduct by the foregoing parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creation of 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.

Regarding advertising risk in the United States in particular, the FTC and states' attorneys general are primarily responsible for enforcing the consumer protection laws by, among other things, investigating and initiating enforcement actions against business practices they deem to be deceptive or fraudulent under applicable laws. We are thus subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products or marketing or advertising efforts. In connection with the marketing or advertisement of our products, we could be the target of claims relating to false, misleading, deceptive or otherwise noncompliant advertising or marketing practices, including under the auspices of the FTC and state consumer protection statutes. If we rely on third parties to provide any marketing and advertising of our products, we could be liable for, or face reputational harm as a result of, their marketing practices if, for example, they fail to comply with applicable statutory and regulatory requirements. We cannot ensure that all marketing materials currently used for our products comply with applicable laws, rules, and regulations, including bans on false and misleading product related claims. Any failure to comply with these restrictions could subject us to assertions of claims of false advertising and misrepresentation, which potentially bring forth significant financial penalties, costly mandatory product recalls, or relabeling requirements, any of which could have a material adverse effect on our results of operations and financial condition.

If we are found to have breached any consumer protection, advertising, unfair competition or other laws or regulations, we may be subject to enforcement actions that generally require us to amend our marketing and business practices in a manner that may negatively impact us. This could also result in litigation, fines, penalties, and adverse publicity that could cause reputational harm and loss of customer trust, which could have a material adverse effect on our business, financial condition and results of operations.

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

Social media, including Instagram, Snapchat, TikTok, Facebook, and Twitter, are increasingly being used to communicate about our products, clinical development programs, and, at present, the conditions our gammaCore therapy is being developed to treat. 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 medical device and wellness industries continue to evolve, and regulations and regulatory guidance relating to such practices are mutable and unclear at times. This evolution creates uncertainty and elevated risk of non-compliance with regulations applicable to our business, which can result in potential regulatory actions against us or potential 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, or 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. Our efforts to promote our products via marketing and social media initiatives may subject us in the future to additional scrutiny of our practices of effective communication of risk information, benefits, or claims, by the FDA, FTC, or both. If any of the aforesaid events were to occur, or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or cause other injury to our business and stockholders.

**Risks Related to COVID-19**

**The ongoing coronavirus pandemic could have a significant negative impact on our business, revenues, financial condition, results of operations, and cash flow, and other epidemics or outbreaks of infectious diseases may have a similar impact.**

The ongoing coronavirus pandemic has impacted, and may continue to impact, our headquarters, manufacturing, and warehousing and ecommerce 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. The ongoing 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 caused us to modify certain of 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 relax, extend, modify, or take further actions that 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 ongoing pandemic crisis and as we make additional adjustments in the eventual transition from it. Implementing new business practices 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; and how quickly and to what extent normal economic and operating conditions 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 any other reasons that may come to light as the coronavirus pandemic continues and associated protective or preventative measures transpire, 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 ongoing pandemic impacts our customers, suppliers, vendors, and other partners, and their financial conditions, but a material effect on any of 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 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 and shipment of our products in certain territories in Europe. We depend on this distributor's efforts; however, 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 require 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 and their effectiveness may be adversely affected by the armed conflict between Ukraine and Russia.

Furthermore, 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.

***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 2023 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 non-compliance with contract terms, over billing, or misconduct. In addition to the above considerations, we have reason to believe that our prospective sales of human performance and general wellness products to the U.S. Armed Forces could involve various significant compliance requirements as regards applicable laws and regulations and certain contract law covenants and conditions that collectively regulate our affairs in the ordinary course of business as a result of our status as a federal contractor.

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. Our qualifying contract on the FSS is scheduled to expire on January 15, 2024. We intend to request an extension of the FSS from the United States Department of Veterans Affair, but there is no assurance the FSS contract will be renewed, if at all on terms favorable to us. 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 governmental policy for such arrangements 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 health. In December 2019, NICE published a Medical Technology Guidance document recommending the use of gammaCore for CH within the NHS. In 2023, we expect NICE to review the guidance document, and any changes in recommendation or pricing may adversely impact our ability to work with NHS England on the MTFM program, which could have an adverse impact on our business in the United Kingdom.

***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 IIT's 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 has 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 potential commercialization of our nVNS platform technology will require substantial additional capital to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and medical device or consumer electronics 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.

***We, or third-party manufacturers on whom we rely, may be unable to successfully sustain and to further scale-up manufacturing of our nVNS technology platform 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 commercialize products, we, or our manufacturers, will need to manufacture products in large quantities.

There are technical challenges to increasing manufacturing capacity, including equipment design, automation, validation and installation, contractor issues and delays, licensing and permitting delays or rejections, materials procurement, manufacturing site expansion, problems with production yields, and quality control and assurance. Continuing to develop or enhance commercial-scale manufacturing facilities could require the investment of substantial additional funds and the hiring and retention of additional management, quality assurance, quality control, and technical personnel who have the necessary manufacturing experience.

The scaling of manufacturing capacity is subject to numerous risks and uncertainties and may lead to variability in product quality or reliability and increased construction timelines and resources required to design, install, and maintain manufacturing equipment, among others, all of which can lead to unexpected delays in manufacturing output. In addition, any changes to manufacturing processes may trigger the need for submissions or notifications to, and in some cases advance approval from, the FDA or other regulatory authorities because of the potential impact of changes on previously cleared, approved, and/or authorized devices. Our facilities are subject to inspections by the FDA and corresponding state agencies on an ongoing basis, and thus, we must comply with Good Manufacturing Practices, which generally require us to maintain compliant processes, controls, and record keeping, and to comply with FDA Quality System Regulations (or QSR), and applicable state-law requirements. We may be unable to adequately maintain, develop, and expand our manufacturing process and operations or maintain compliance with FDA and state agency requirements, and manufacturing issues could impact our cleared and approved products. If we are unable to manufacture a sufficient supply of our current products or any future products for which we may receive approval or clearance, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand, contractual obligations, and our business will suffer.

In light of the above considerations, 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, if appropriate, of our nVNS technology platform 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 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 nVNS technology platform 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 nVNS technology platform 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, 2022, we had approximately $4.2 million of inventory. Our inventory significantly exceeds current demand for the nVNS technology platform, which also could result in an increased risk of adverse financial impact from inventory obsolescence. There are, however, risks that growth in our business, including our recently launched non-prescription, human performance and wellness offerings, may result in demand that could outstrip our current inventory, in which case we would be subject to various supply chain, manufacturing, and operational risks. If not mitigated fully, this could negatively impact our ability to commercialize our products and have a material adverse effect on our brands, revenues, expenses, results of operations, and financial condition.

**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 require 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 the development is completed, whether it 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 brands 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 competent jurisdiction may find our patents invalid and/or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services 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 of 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 and 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 operations, or financial condition.

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 operations, or financial condition.

***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 and business could be adversely affected.

***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 involve 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 other 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 depend 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 non-compliance 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, which 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, 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 are 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 because 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.

***The regulatory environment governing information, cybersecurity, and privacy is increasingly demanding and continues to evolve.***

The regulatory environment governing information, cybersecurity, and privacy is increasingly demanding and continues to evolve.

Personal privacy and data security have become significant issues in the U.S., Europe, and many other jurisdictions where we offer our products. The regulatory framework for privacy and security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future.

Certain U.S. and foreign laws, such as the federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA), govern the transmission, security, and privacy of individually identifiable information and sensitive health and other personal information that we may obtain or have access to in connection with the operation of our business, including the conduct of clinical research trials or other research studies that may provide us with access to this information. We may be required to make costly system modifications to comply with these data privacy and security requirements. In addition, if we do not properly comply with applicable laws and regulations related to the protection of this information, we could be subject to criminal or civil penalties and sanctions. The California Consumer Privacy Act of 2018 (or CCPA), which became effective on January 1, 2020, requires us to make new disclosures to consumers about our data collection, use, and sharing practices. The CCPA also allows consumers to opt out of certain data sales to third parties, affords new consumer rights, and provides a new cause of action for data breaches with the possibility of significant statutory damage awards as well as injunctive or declaratory relief if there has been unauthorized access, theft, or disclosure of specified personal information due to failure to implement reasonable security procedures. The California Privacy Rights Act (or CPRA), which went into effect on January 1, 2023, with a 12-month look-back period for enforcement purposes, will effectively replace the CCPA. Among other changes, the CPRA expands consumers' rights and has enhanced enforcement mechanisms, such as the creation of a new California privacy agency that will investigate and enforce the CPRA and its promulgating regulations. In addition to the CCPA and the CPRA, all 50 U.S. states have data breach notification laws that, if violated, could result in penalties, fines, and litigation. In addition, many states have implemented or are in the process of implementing related legislation, including state-specific biometric privacy laws that have resulted in class-action lawsuits against businesses. The full impact of these laws on our business is yet to be determined, but it could result in increased operating expenses and additional exposure to the risk of litigation by or on behalf of consumers.

Internationally, the General Data Protection Regulation ( or GDPR) took effect in May 2018 within the European Economic Area (EEA), and many EEA jurisdictions have also adopted their own data privacy and protection laws in addition to the GDPR. Furthermore, other international jurisdictions, including Singapore, South Korea, China, Brazil, Mexico, and Australia, have also implemented laws relating to data privacy and protection. Although we believe that we are complying with the GDPR and similar laws, these laws are still relatively new. Therefore, as international data privacy and protection laws continue to evolve, and as new regulations, interpretive guidance, and enforcement information become available, we may incur incremental costs to modify our business practices to comply with these requirements. In addition, our internal control policies and procedures may not always protect us from reckless, intentional and/or criminal acts committed by our employees or agents.

**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 and our general wellness products, Truvaga and TAC-STIM to market in the United States and to expand the use of our gammaCore therapy to additional therapeutic indications, and to expand the reach of our wellness initiatives.***

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 (FDCA) 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 requirements;
- health information privacy and security laws, 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
- State of New Jersey Department of Health Services legal requirements.

Government regulation may impede our ability to conduct clinical trials and 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. For instance, 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. We have recently reduced resources in research and development which may delay our receipt of regulatory approvals for additional indications. 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. Moreover, any reclassification, redesignation, or new regulatory treatment of our existing general wellness products in light of applicable law, nonbinding recommendations or other inferences resulting from complex legal analysis and interpretation of the existing regulatory framework governing wellness products and their relational position in the larger FDA scheme of enforcement may negatively impact our marketing and other activities in respect to our wellness and human performance products, Truvaga and TAC-STIM, respectively, and other future marketing and other activities in respect to future wellness business ventures.

Even though 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 competitive and financial position.

The advertising, marketing, and labeling of medical devices are highly regulated by the FDA and 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 agencies. Our general wellness product activity is also subject to similar marketing and promotion risk.

In 2009, the FTC promulgated nonbinding Guides Concerning the Use of Endorsements and Testimonials in Advertising (or Endorsement Guides), which explained what endorsement practices the FTC views as being unfair or deceptive acts or practices. In 2020, the FTC sought public comments in connection with informal, notice and comment rulemaking on whether the Endorsement Guides should be amended in various ways. The last time the FTC sought similar public comments led to a major revision of the Endorsement Guides. Consequently, the FTC could bring an enforcement action based on practices that are possibly inconsistent with the current Endorsement Guides as the FTC considers any revisions. Under the current Endorsement Guides, advertisements that feature a consumer and convey his or her atypical experience with a product or service are required to clearly disclose the typical results that consumers can generally expect. We cannot be sure that the FTC will not challenge our advertising or other operations in the future, which could have a material adverse impact on our business.

Furthermore, as a general matter, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business and prospects for growth. 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 for an unknown period of time. Compliance obligations under the various domestic and foreign regulations are oftentimes complex and onerous, which contributes to a risk that we could be found to be not compliant with particular requirements. The risk of being found in violation of applicable domestic and foreign regulations, as a consequence of public law-based adjudicatory or other processes (such as administrative law hearings), is further increased by the fact that many of them have not been comprehensively interpreted by regulatory agencies or judicial authorities, particularly with respect to new and emerging technologies, and regulatory provisions are typically open to various interpretations and possible juridical doctrines in certain jurisdictions that imbue greater authority to interpret the law to regulatory authorities under certain conditions or standards.

Any significant developments in the FDA or foreign regulatory approval standards and processes, including both legal and policy changes, could also delay, or preclude, the clearance or approval of our products submitted for review. For example, in the United States, as part of the 21st Century Cures Act passed in 2016, Congress enacted several reforms that affect medical device regulation both pre- and post-approval, and FDA implementation and development of guidance in many areas are ongoing. In August 2017, Congress enacted the FDA Reauthorization Act of 2017 (or FDARA), which reauthorized the FDA to collect device user fees, including a new user fee for de novo classification requests, and contained substantive amendments to the device provisions of the FDCA. Among other changes, FDARA mandated that the FDA update and revise its processes for scheduling inspections of device establishments, communicating about those inspections with manufacturers, and providing feedback on the manufacturer's responses to Form 483s. The statute also mandated that the FDA study the impact of device servicing, including third-party services, and created a new process for device sponsors to request classification of accessory devices as part of the PMA application for the parent device or to request a separate classification of accessory devices. In addition, the FDA is reportedly in the process of reviewing the 510(k) approval process and criteria and has announced initiatives to improve the current pre- and post-market regulatory processes and requirements associated with infusion pumps and other home-use medical devices, for instance, and, as part of such review efforts, the FDA is evaluating adverse event reporting and recall processes for insulin pumps.

Generally, 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. The data contained in our submissions, including data drawn from our clinical trials, may not be sufficient to support clearance or approval of our products or additional or expanded indications. Medical device company stock prices have declined significantly in certain circumstances where companies have failed to meet expectations in regard to the timing of regulatory approval. If the FDA's response causes product approval delays, or is not favorable for any of our products, our stock price could decline substantially. It is uncertain how potential changes to FDA regulatory approval standards and processes may impact our ability to gain clearance or approval from FDA for our products in the future.

***We depend heavily on revenue from the Department of Defense and the Department of Veterans Affairs for a substantial portion of our business. Changes in the U.S. Government's priorities, or delays or reductions in spending could have a material adverse effect on our business.***

Approximately 60.8% of our revenues from operations in fiscal 2022 were from sales directly or indirectly to the programs with the U.S. Department of Defense, primarily the Department of Veterans Affairs, and to a lesser extent the U.S. Air Force.Cost cutting including through consolidation and elimination of duplicative organizations and insurance has become a major initiative for Department of Defense. The funding of our programs may be subject to the overall U.S. government budget and appropriation decisions and processes which are driven by numerous factors, including geo-political events and macroeconomic conditions. Spending levels by government authorities we do business with can be increasingly difficult to predict and are expected to be affected by numerous factors. Such factors include priorities of the Biden administration and the Congress, and the overall health of the U.S. and world economies and the state of governmental finances.

We expect that budgetary constraints and concerns related to spending and the national debt will continue to place pressure government spending levels, which could adversely impact funding for purchase of certain of our products, our operations, financial results and growth prospects.

***Our future success in part 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 payors 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 U.S., EEA, and foreign governmental agencies and authorities regulate and oversee, among other things, with respect to medical devices:

- design, development, and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- risk assessment, and management;
- marketing, sales and distribution;
- pre-market regulatory clearance and approval;
- conformity assessment procedures;
- record-keeping procedures;
- advertising and promotion;
- recalls and other field safety corrective actions, and in the case of the FDA, for example, if the FDA subsequently determines that a report was required for such recall or other field correction action that was not submitted, any subsequent related enforcement 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 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 became applicable on May 26, 2021, with the transition period intended to end on May 26, 2024. While progress has been made on the transition from the MDD to the MDD, a European Commission proposal published on January 6, 2023, stated that the overall number and capacity of conformity assessment (a.k.a., ‘notified’) bodies remains insufficient to carry out the tasks required of them. In addition, many manufacturers are not sufficiently prepared to meet the strengthened requirements of the MDR by the end of the transition period. This is threatening the availability of medical devices on the EU market. According to an estimation presented by notified bodies to the Medical Device Coordination Group on November 17, 2022, the number of certificates issued by May 2024 may reach around 7,000 if the current rate of certificate issuance remains the same with no changes to current conditions. Notified bodies estimate that the transition of all Directives’ certificates to MDR certificates could possibly be completed by December 2027. The European Commission’s “Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, Brussels, 1.6.2023 intends” to extend the transition period from May 26, 2024 until December 31, 2027 for high-risk Class III and Class IIb implantable devices, and until December 31, 2028 for medium and lower risk Class IIb and Class IIa devices. The gammaCore products (gammaCore Sapphire and gammaCore-S) are EU Class IIa devices. Once applicable, the new regulations will among other things:

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

Once applicable, the 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 significant business and legal uncertainty and potentially divergent national laws and regulations in the EU and the United Kingdom. Given the lack of comparable historical precedent, it is unclear what Brexit's financial, regulatory, and legal implications would be, and how Brexit would ultimately 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. Importantly, 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. Lastly, 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, market, and sell these products could suffer, and, if our general wellness products no longer fall under the scope of applicable FDA guidance, such products may be subject to additional and more comprehensive regulation and/or greater regulatory uncertainty, affecting our ability to commercially distribute, market, and sell such products in the ordinary course of business.***

Any of our medical device 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 FDCA, 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 general wellness products, Truvaga and TAC-STIM, which in the future may or may not be low risk general wellness products in light of applicability of, and potential, revisions to FDA guidance for such products, and which are not intended for medical use, and which we believe appropriately fall under the scope of current FDA guidance applicable to such products, are not normally subject to the rigorous regulatory processes described in the aforementioned paragraphs. Therefore, some of our products, or product features in certain circumstances, may not be subject to the aforesaid Section 510(k) process and/or other regulatory requirements in accordance with specific FDA guidance and policies. In addition, some of our products, or product features, may not be subject to statutory device prescription requirements pursuant to various provisions of the FDCA.

Section 3060(a) of the 21st Century Cures Act amended Section 520 of the FDCA on December 13, 2016, removing certain software functions, including those intended for maintaining or encouraging a healthy lifestyle that are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, from the definition of device in Section 201(h) of the FDCA. Section 520(o)(1)(B) of the FDCA states that software that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition" is not a device under section 201(h) of such enactment. In connection with the aforesaid legislative developments, the FDA has issued the aforementioned general wellness guidance in July 2016 and the reissued guidance in 2019, clarifying at each time the FDA's interpretation of this provision and its application to general wellness products (as defined by the Center for Devices and Radiological Health, which for the purposes of the current guidance mean products that are intended for only general wellness use, as defined in the current general wellness guidance, and that present a low risk to the safety of users and other persons). We recognize that the FDA's guidance documents, including the current general wellness guidance on low risk, general wellness products, do not create legal obligations. Instead, guidance documents describe the FDA's contemporary thinking on a topic, which is subject to change, and should be viewed only as legally nonbinding recommendations, unless particular regulatory or statutory requirements are cited to the make the contrary inference. In light of this information, we also recognize that the current guidance does not change or otherwise rescind any legally enforceable requirements of the FDCA or any applicable regulations. Moreover, we acknowledge that the FDA's general wellness guidance in this respect does not prohibit the FDA from consulting with the Consumer Product Safety Commission (or CPSC) as to whether or not a general wellness product is a consumer product under the CPSC's authority or a device. The FDA may coordinate with other agencies and authorities, such as the CPSC, in ascertaining appropriate jurisdiction over products. If a product is a device under Section 201(h) of the FDCA, it is generally excluded from CPSC's authority over "consumer products" as contemplated under the Consumer Product Safety Act, particularly under Section 2052(a)(5)(ii)(H). However, CPSC and the FDA may both assert jurisdiction over certain medical devices under other statutory authorities the CPSC is charged with implementing.

Subject to continuing analysis and review of considerations included in the FDA, general wellness guidance and any revisions to such guidance and other guidance, we have applied or otherwise made use of the guidance questions in Section 4 of the published FDA low risk, general wellness products guidance document, which assist in determining whether general wellness products are within the scope of such guidance, among other legal review. We acknowledge that such questions should be read in the context of the full written text of the guidance and represent, but do not constitute in and of themselves, the framework described in such guidance. Main considerations, including whether a product has an intended use that relates to maintaining or encouraging a general state of health or healthy activity, whether a product has an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions, whether the product is low risk in that it is not invasive, and not implanted, and does not involve a technology that may pose a risk to the safety or users or other persons if specific regulatory controls are not applied, among other considerations, are particularly relevant to our business involving general wellness products. Descriptions of general wellness products in the aforementioned FDA guidance within Section 3 of the published document are also particularly relevant to our business involving general wellness products. We further acknowledge that the Center for Devices and Radiological Health's general wellness policy applies only to general wellness products that are deemed to be low risk. In considering whether a product of ours is low risk for purposes of the aforementioned FDA guidance, the FDA recommends the due consideration of whether the Center for Devices and Radiological Health actively regulates products of the same type as the product in question, and this consideration is important to our current and future wellness market engagement.

Our business activities involving general wellness products, Truvaga and TAC-STIM may be subject to significant and possibly material and adverse consequences if revisions to FDA guidance or other guidance modify our reasoned beliefs and opinions regarding classification, other legal questions, and compliance with all applicable rules and regulations that apply to our business activities in various ways. Moreover, FDA may disagree with our assessment, potentially subjecting these products to regulation as medical devices. We and our legal advisors strive to regularly keep abreast of all relevant developments in the statutory, administrative, and decisional laws, on federal and, where applicable, state levels, that which influence or inform our general wellness products-related development, marketing, promotion, distribution, and sale, among other activities. In light of the substantial complexity in such laws as well as their potential actual interactive Ness, or perceived overlap or conflict, with the application of the FDA's existing regulatory approval or clearance processes for medical device products as a result of either official agency changes to applicable wellness guidance, our subsequent legal review of such guidance that differs substantially from earlier legal review of such guidance, or the FDA's disagreement with our determination regarding the regulatory status of our general wellness products, we may experience adverse and possibly material effects on our ability to commercialize our general wellness products, which could impact our financial condition, operating results, and prospects for growth. Separate and apart from our legal and compliance functions and external advisors, we maintain internal controls and policies and procedures that militate against compliance risk in our wellness line of business and train and educate our sales agents and other personnel on subject matter pertinent to compliance with relevant law in various jurisdictions.

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 any such future products would adversely affect our overall 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, including FDA orders to repair, replace, or refund the cost of devices, 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, or interruption of the supply of components from our key component suppliers;
- 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 U.S. 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. We may also decide to recall a product voluntarily if we find a material deficiency, including unacceptable risks to health, manufacturing defects, design errors, component failures, labeling defects, or other issues. Recalls of our products could divert the attention of our management and have an adverse effect on our reputation, financial condition, and operating results. 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. With regard to QSR administration, the FDA may enforce this regulation through announced (through prior notification) or unannounced inspections that pertain to several facets of our methods and documentation processes of the design, testing, production, control, selection, and oversight of suppliers or contractors; quality assurance; labeling; packaging; storage; complaint handling; shipping; and servicing of our products.

***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 in adults, CH prevention, the preventive and acute treatment of migraine headache in the United States in adults and adolescents, and the treatment of Paroxysmal Hemicrania, or HC, in adults. We may only promote or market our gammaCore 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 our educational, promotional, and marketing practices in various ways 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.

While certain U.S. courts have held that truthful, non-misleading, off-label information is protected under the First Amendment under certain circumstances, the FDA continues to take the position that off-label promotion is subject to possible enforcement action. It is also conceivable that other federal, state, or foreign enforcement authorities may take action if they consider our communications, including promotional or training materials, to constitute promotion of an uncleared or unapproved use. If not successfully defended, enforcement actions related to off-label promotion could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In any such event, our reputation could be damaged, adoption of our products could be impaired and we could be subject to extensive fines and penalties.

Additionally, we must have adequate substantiation for the claims we make for our products. If any of our claims are determined to be false, misleading or deceptive, our products could be considered misbranded under the FDCA or in violation of the Federal Trade Commission Act. We could also face lawsuits from our competitors under the Lanham Act alleging that our marketing materials are false or misleading.

In some instances in our advertising and promotion, we may make claims regarding our products relative to competing products, which may subject us to heightened regulatory scrutiny, enforcement risk, and litigation risks.

For instance, the FDA applies an elevated level of review to comparative claims when applying its statutory standards for advertising and promotion, particularly with regard to the requirement that promotional labeling be truthful and not misleading. Differing interpretations as to whether certain communications are consistent with a product's FDA-required labeling may be more likely in some cases than others, and so, the FDA customarily evaluates communications on a fact-specific basis.

In addition, making comparative claims may draw concerns from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor, or that the competitor's product is inferior, this creates legal risk in that the competitor has possible legal remedies under federal and state false advertising or unfair and deceptive trade practices law (and possibly also state libel law). Such litigation ordinarily implicates relief in equity, such as injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by applicable law.

The advertising and promotion of our products is also 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.

Notwithstanding the risk of legal liability in connection with claims or actions alleging misleading or comparative advertising and promotion, in foreign jurisdictions, we can market a product only if we receive a marketing authorization in the first place and, in some cases, pricing approval, from the appropriate regulatory authorities. The marketing authorization procedures vary among countries and can involve additional testing, and the time required to obtain any required authorization or approval may differ from that required to obtain FDA marketing authorization(s). Foreign regulatory authorization or approval processes may include all of the risks associated with obtaining FDA marketing authorization(s) in addition to other risks. We may not obtain foreign regulatory authorizations or approvals on a timely basis, if at all. Obtaining a marketing authorization from the FDA does not ensure authorization or approval by regulatory authorities in other countries will follow, and authorization or approval by one foreign regulatory authority does not ensure authorization or approval by regulatory authorities in other foreign countries or by the FDA. In addition, in order to obtain the authorization to market our products in certain foreign jurisdictions, we may need to obtain a Certificate to Foreign Government from the FDA. The FDA may refuse to issue a Certificate to Foreign Government in certain instances, including without limitation, during the pendency of any outstanding warning letter. As a result, we may not be able to file for regulatory approvals or marketing authorizations and may not receive necessary approvals or authorizations to commercialize our products in any market outside the United States on a timely basis, or at all.

***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 non-compliance 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.

Product recalls may materially and adversely affect consumer confidence in our brand and lead to decreased customer demand for our products. Product recalls, withdrawals, or seizures also may lead to increased scrutiny of our operations by federal, state, or international regulatory agencies and increased litigation. Both outcomes could have material adverse effects on our business, results of operations, and financial condition.

***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 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 introduced substantial changes to the obligations with which medical device manufacturers must comply within 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 payors 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 payors.

- 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 payors. 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;

- HIPAA, as amended, 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

- FCPA and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business;

- 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 payor, 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 are 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-consuming and costly 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, for example. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

We have implemented policies and procedures designed to ensure compliance with applicable global laws and regulations, but there can be no assurance that we will be in continuous compliance with all relevant domestic and global regulations, given their multitude, complexity, and changeable nature. 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.

***Breakthrough Designation from the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our devices.***

The FDA's Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

While our gammaCore nVNS device has received Breakthrough Designation from the FDA for the treatment of posttraumatic stress disorder, or PTSD, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Breakthrough Device designation if it believes that the Designation is no longer supported by data from our clinical development program.

***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 overall demand for our products.

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, 2022, 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, 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.

***ESG matters, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition, and operating results and may damage our reputation.***

Companies across all industries are facing increasing scrutiny regarding their environmental, social, and governance practices. In particular, we expect many customers will continue to indicate preferences for buying products that are sustainably and responsibly grown and/or made. Changing and unpredictable preferences in this manner may result in increased interest in the sourcing or origin of our components, the recyclability of our products, and the environmental impact of our supply chain, among other areas of interest. Such preferences could require additional transparency, due diligence, and public reporting and could cause us to incur additional costs or to make changes to our business operations. We may also determine that certain changes are required in anticipation of further evolution of consumer preferences and demands. Increased focus on ESG matters may also result in investors reconsidering their investment decisions as a result of their particular assessments of a company's ESG practices. Moreover, concern over climate change and other environmental sustainability matters has resulted and may in the future result in new or elevated legal and regulatory requirements to reduce or militate against certain impacts to the environment, including greenhouse gas emissions regulations, alternative energy policies, and sustainability initiatives, such as single use plastics. Increased regulatory requirements may be more complex and detailed relative to any sustainability measures we may be currently undertaking or may consider implementing in the future and may cause disruptions in the supply and manufacture of our products or an increase in operating costs. If we fail to achieve any goals, targets, or objectives we may set with respect to ESG matters, if we do not comply with new regulations and laws or meet evolving consumer, investor, industry, or other stakeholder expectations and standards, including those related to potential reporting, or if we are perceived to have not responded appropriately to a growing concern for ESG matters, we may face public or private legal or regulatory actions; the imposition of fines, penalties, or other sanctions; adverse publicity; and decreased total demand from certain customers who may cease buying our products, and the price of our stock could decline. Any of these possible results could adversely and materially harm our reputation or have a materially significant effect on our business, financial condition, or operating results.

**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 negativelyimpact the market price and liquidity of our common stock and our ability to access the capital markets.***

On February 13, 2023, we held a special meeting of stockholders at which the stockholders approved an amendment to the Company's certificate of incorporation to implement a reverse split of our common stock (the "Reverse Stock Split") which became effective February 15, 2023. The purpose of the Reverse Stock Split was to seek to increase the price of the common stock and thereby to regain compliance with the minimum closing bid price of $1.00 per share for 10 consecutive trading days as required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Rule"). On March 6, 2023, we received a letter from Nasdaq confirming that our common stock had regained compliance with the Bid Price Rule, and as a result, our common stock will continue to be listed on the Nasdaq Capital Market.

Any Nasdaq action relating to a delisting could 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 such delisting action may materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Capital Market could also have other negative results, including the potential loss of institutional investor interest and fewer business development opportunities.

In the event of any delisting or potential delisting, we may attempt to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to remain listed or be re-listed, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Bid Price Rule or prevent future non-compliance with Nasdaq's listing requirements.

***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 ("Securities Act") and the Securities Exchange Act of 1934 ("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, 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 of 2002 ("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 $1.235 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 662/3% 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 662/3% 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 (or the DGCL). 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 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;

- 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 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 DGCL, 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 such act or the rules and regulations promulgated 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 adopted 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 of 2010 (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 Annual Report 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 for our products;
- 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 and wellness industries 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 U.S.;
- 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 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 our stock price, if our operating results fail to meet the expectations of analysts, would likely decline. If one or more of these analysts cease coverage of us or fail to publish research 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. Shares that 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 in the United States. 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 that could affect our tax burden could be enacted by a governmental authority. We cannot predict the timing or extent of such tax-related developments that 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 Tax Cuts and Jobs Act, 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 Tax Cuts and Jobs Act will not negatively impact our operating results, financial condition, or our future business operations. This Annual Report 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.

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 expense 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 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, NJ. Since the spring of 2020, as a result of COVID-19, our employees previously based in Basking Ridge generally have conducted business remotely. In the fourth quarter of 2020, we formally vacated the Basking Ridge, NJ 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 include present and past directors and officers, Evercore Group L.L.C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for our IPO; and two of our stockholders. On August 15, 2019, the Superior Court entered an order consolidating the Kuehl and Stone actions, which 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 has been 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 forum selection clause in our certificate of incorporation's. 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 the supplemental motion to dismiss based on the federal forum selection clause with prejudice and granted the original motion to dismiss without prejudice. On January 27, 2022, the plaintiffs filed a notice of appeal to the Appellate Division. On April 15, 2022, the plaintiffs filed their appeal brief. The brief of defendant-appellees was filed on May 16, 2022. The appeal is fully briefed. Oral argument is scheduled for April 19, 2023.

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

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 plaintiffs filed a second amended complaint. On November 17, 2021, the defendants moved to dismiss the new complaint. Briefing on the motion was complete on January 7, 2022. On July 5, 2022, the case was reassigned to Judge Zahid N. Quraishi, who has ordered that he will consider the pending motion to dismiss in due course. Argument of the motion has not yet been scheduled.

On March 4, 2021, purported stockholder Richard Maltz 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 our bylaws and certificate of incorporation.

On March 8, 2021, purported stockholder Erin Yuson brought a purported stockholder derivative action in the United States District Court for the District of New Jersey. The action is captioned *Erin 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 our bylaws and certificate of incorporation.

The plaintiffs 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. These cases also have been re-assigned to Judge Quraishi.

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.

We are subject to various claims, complaints, and legal actions in the normal course of business from time to time. We are not aware of any further currently pending litigation for which it believes the outcome could have a material adverse effect on its operations or financial position. We expenses associated legal fees including those relating to the stockholder litigation described in Note 13 in the period they are incurred.

**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, 2023, there were 333 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.*

Note: Information concerning the shares of our common stock and related share prices in this Item 7 has been adjusted to reflect the 1-for-15 reverse split of our common stock that was made effective on February 15, 2023. (See, "Item 8 – Notes to consolidated financial statements – Note 2 - Basis of Presentation").

**Overview**

We are a commercial stage bioelectronic medicine and wellness company dedicated to improving health through our non-invasive vagus nerve stimulation ("nVNS") technology platform. Our focus is the commercialization of medical devices for the management and treatment of certain medical conditions and consumer product offerings utilizing nVNS to promote general wellbeing and human performance in the United States and select overseas markets.

nVNS is a platform bioelectronic technology that modulates neurotransmitters and immune function through its effects on both the peripheral and central nervous systems. Our nVNS treatment is delivered through a proprietary high-frequency burst waveform that safely and comfortably passes through the skin and stimulates therapeutically relevant fibers in the vagus nerve. Various scientific publications suggest that VNS works through several mechanistic pathways including the modulation of neurotransmitters.

Historically, vagus nerve stimulation or VNS, required an invasive surgical procedure to implant a costly medical device. This limitation has generally limited VNS from being used by anyone other than the most severe patients. Our medical devices and wellness products are self-administered and intended for regular or intermittent use over many years.

Our business is supported by our in-house capabilities spanning research and development, regulatory affairs and compliance, sales and marketing, product testing, assembly, fulfillment, and customer support. We derive revenues from the sale of medical devices and wellness products in the United States and select overseas markets. We have two principal product categories:

- Handheld, personal use medical devices for the management and treatment of certain medical conditions; and
- Handheld, personal use consumer product offerings utilizing nVNS technology to promote general wellbeing and human performance.

We believe our nVNS treatment may be used in the future to effectively treat additional medical conditions or improve human performance.

Our goal is to be a leader in non-invasive neuromodulation by using our proprietary nVNS platform technology to deliver better health. To achieve this, we offer multiple propositions:

- gammaCore for the treatment of certain medical conditions such as primary headache;
- Truvaga for the support of general health and wellbeing; and
- TAC-STIM for human performance as defined by the United States Air Force Research Laboratory.

Our flagship model, gammaCore Sapphire, is a prescription medical device currently FDA cleared for a variety of primary headache conditions. gammaCore is available by prescription only and Sapphire is a portable, reusable, rechargeable and reloadable personal use option for patients to use at home or on the go. Prescriptions are written by a health care provider and dispensed from a specialty pharmacy, through the patient's healthcare system, or fulfilled directly to certain patients directly from our facility in Rockaway, NJ. After the initial prescription is filled, access to additional therapy can be refilled for certain of our gammaCore products periodically through the input of a prescription-only authorization.

Truvaga is a personal use consumer electronics wellness product that does not require a prescription and is available direct-to-consumer from electroCore at www.truvaga.com. Truvaga is not intended for medical use. TAC-STIM is a form of nVNS for human performance and has been developed in collaboration with the United States Department of Defense Biotech Optimized for Operational Solutions and Tactics, or BOOST program. We are exploring strategies to make this product offering available to other branches of the active-duty military and certain human performance professionals in the United States and abroad.

TAC-STIM is available as a Commercial Off the Shelf (COtS) solution to professional organizations and is the subject of ongoing research at the United States Air Force Research Laboratory. TAC-STIM is not intended for medical use.

We have generally focused most of our historical sales efforts in two channels, the United States Department of Veterans Affairs and United States Department of Defense, or VA/DoD, and the United Kingdom utilizing our FDA cleared and CE marked product, gammaCore.

The United States Department of Veteran Affairs comprised 60.8 % of our revenue during the year ended December 31, 2022. We expect that a majority of our 2023 sales 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 the government channels. The FSS is scheduled to expire on January 15, 2024. We intend to request an extension of the FSS from the United States Department of Veteran Affairs, but there is no assurance the FSS will be renewed, and if at all renewed at terms favorable to us. Our sales function in this channel is comprised of employees and independent contractors.

Sales under the MTFM program for cluster headache in the UK comprised 15.1% of our revenue during the year ended December 31, 2022. In 2023, we plan on continued expansion under this program, as well as continue to utilize distribution partners to commercialize our nVNS technology in territories outside the United States and United Kingdom. In 2023, we expect NICE to review the guidance document and any changes in recommendation or pricing may adversely impact our ability to work with NHS England on the MTFM program.

We believe there may be significant opportunities beyond these areas. In 2023, therefore, we plan to continue our investment in expanded commercial adoption of gammaCore with cash pay, physician dispense, and direct-to-consumer approaches, and continue our early efforts to begin building wellness and human performance propositions through Truvaga and TAC-STIM.

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

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

Our expected cash requirements for the next 12 months and beyond are based on the commercialization success of our products and our ability to control operating expenses. There are significant risks and uncertainties as to our ability to achieve these operating results, including as a result of the potential adverse impact on our business from the ongoing COVID-19 pandemic. Due to these risks and uncertainties, we may need to reduce our activities significantly more than our current operating plan and cash flow projections assume in order to fund operations for the next 12 months. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and, ultimately, potentially cease operations. These conditions raise substantial doubt about our ability to continue as a going concern. See “Liquidity and Capital Resources.”

***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. If we raise additional funds by issuing equity or debt securities, either through the sale of securities pursuant to a registration statement or by other means, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders.

On July 2, 2021, we completed a public offering of 1,380,000 shares of our common stock at a purchase price of $15.00 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 63,479 shares of common stock, at a purchase price of $15.75 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 13,333 shares of our common stock in connection with the lease termination related to our former headquarters located in Basking Ridge, NJ.

***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 2022, we announced the launch of an ecommerce 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.

In 2022, we continued executing on the plan to expand international distribution by onboarding exclusive distribution partners outside the United States and United Kingdom. On March 29, 2022, we entered into an agreement with Teijin Limited (Teijin), to license certain exclusive rights to its nVNS technology for commercialization in Japan for a range of primary headache disorders. Under the agreement, we received a non-refundable, upfront payment for the licenses and rights granted to Teijin. We began to recognize revenue for this upfront payment ratably over a period of one year commencing in the second quarter of 2022.The financial terms of the Teijin license agreement contain milestone payments, payable upon the decision by Teijin to commercialize the licensed product for specific indications. We will also receive an annual license fee commencing on the first anniversary of the agreement and payable annually until the first commercial sale on any approved indication. Upon favorable regulatory and payor coverage decisions in Japan, the parties plan to enter into an exclusive commercial supply agreement for gammaCore nVNS. The agreement contains customary terms and conditions, including renewal and termination provisions, as well as minimum purchase commitments once a commercial supply agreement is in place. Furthermore, Teijin is responsible for all costs associated with regulatory approval by the Pharmaceuticals and Medical Devices Agency (PMDA), the Japanese FDA equivalent. As part of the agreement, Teijin will have the right of first negotiation for a license to additional indications in Japan.

***Impact of COVID-19***

The ongoing coronavirus pandemic has impacted, and may continue to impact, our headquarters, manufacturing, and warehousing and ecommerce 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. The ongoing 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 caused us to modify certain of 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 relax, extend, modify, or take further actions that 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.

**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 or as 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, as well as purchase orders for open market sales to 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 2022 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 was 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 health.

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 ecommerce 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 cash pay models through direct-to-physician and direct-to-consumer channels and our ecommerce 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.

***Licensed Products***

We license a portion of our devices through our cash pay channels. The cost of these licensed devices is capitalized and included in Other Assets in our Balance Sheet at December 31, 2022 and 2021, and is being recognized as cost of goods sold over the estimated useful life of the device. If certain licensed devices are returned and no longer meet quality specifications or the carrying amount of certain licensed devices are no longer deemed to be recoverable, we record a charge to cost of goods sold to write down such licensed devices to zero.

***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. The fair value of each stock option award granted was estimated on the date of grant using the Black-Scholes model. Since our common stock was not publicly traded until June 2018 there has been insufficient volatility data available. Accordingly, we have used an expected volatility based on historical common stock volatility of our peers. Beginning in December 2022, we began incorporating our historical common stock volatility at a weighting of 50% of the total composite volatility rate. During 2023, the Company will continue to evaluate the volatility rate used to value stock options. 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 $1.235 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, 2022 and 2021*

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021 with the changes in those items in dollars.

| | Years ended December 31, | | |
|---|---|---|---|
| **(in thousands)** | **2022** | **2021** | **Change** |
| Net sales | $ 8,592 | $ 5,451 | $ 3,141 |
| Cost of goods sold | 1,616 | 1,385 | 231 |
| Gross profit | 6,976 | 4,066 | 2,910 |
| Operating expenses: | | | |
| Research and development | 5,520 | 2,536 | 2,984 |
| Selling, general and administrative | 24,330 | 21,573 | 2,757 |
| Total operating expenses | 29,850 | 24,109 | 5,741 |
| Loss from operations | (22,874) | (20,043) | (2,831) |
| Other (income) expense: | | | |
| Gain on extinguishment of debt | — | (1,422) | 1,422 |
| Gain on termination of joint venture | — | (549) | 549 |
| Interest and other income | (287) | (11) | (276) |
| Other expense | 6 | 8 | (2) |
| Total other (income) expense | (281) | (1,974) | 1,693 |
| Loss before income taxes | (22,593) | (18,069) | (4,524) |
| Benefit from income taxes | 431 | 851 | (420) |
| Net loss | $ (22,162) | $ (17,218) | $ (4,944) |

***Net Sales***

Net sales for the year ended December 31, 2022 increased 58% as compared to the year ended December 31, 2021. The increase of $3.1 million is due to an increase in net sales across all major channels including the U.S. Department of Veteran Affairs, U.S. commercial channel, and sales from outside the U.S. which includes licensing revenue of $139,000.There was no licensing revenue in the comparable prior year. Revenue from outside the U.S. was adversely impacted due to the strengthening of the U.S. dollar during the last half of 2022. We expect that the majority of 2023 fiscal year revenue will continue to come from the U.S. Department of Veterans Affairs and United Kingdom. Additionally, we expect revenues to expand from our cash pay propositions which includeecommerce stores, direct to physician models for 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, sports medicine, functional and integrative medicine professionals, as well as chiropractors, and PharmDs (Doctors of Pharmacy). In addition, we believe we may generate additional revenue from sales of our Truvaga and TAC-STIM products.

***Gross Profit***

Gross profit increased $2.9 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. Gross margin was 81% and 75% for the years ended December 31, 2022 and 2021, respectively. Our evolving commercial strategy has resulted in the launch of cash payment models under which we license a portion of our devices. The cost of the licensed device is being recognized as cost of goods sold over the estimated useful life of the device. The increase in gross margin was primarily due to the favorable impact on gross margin associated with the licensing of a portion of our devices in the year ended December 31, 2022. Moreover, in 2022, we sold an increasing amount of longer duration therapy, resulting in a higher average selling price, as well as selling an increased number of refill kits with a lower cost of goods. These factors, including Teijin license revenue with no associated cost of goods, contributed to the increase in gross margin. Gross profit and gross margin in 2023 will be largely dependent on revenue levels, product mix, and any changes in the estimated useful lives of licensed devices.

***Research and Development***

Research and development expense of $5.5 million for the year endedDecember 31, 2022 increased by $3.0 million. This increase was primarily due to targeted investments to support the future iterations of our therapy delivery platform, including the use of our intellectual property around the delivery of smart phone-integrated and smart phone-connected non-invasive therapies. In 2023, we plan to continue to invest in the next generation of our therapy delivery platform.

***Selling, General and Administrative***

Selling, general and administrative expense of $24.3 million for the year ended December 31, 2022 increased by $2.8 million as we continued to make targeted investments to support our commercial efforts, particularly around sales and marketing efforts for our cash pay propositions which include ecommerce stores, direct to physician models for 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, sports medicine, functional and integrative medicine professionals, as well as chiropractors, and PharmDs (Doctors of Pharmacy). In 2023, we plan on continuing to make targeted investments in sales and marketing to support our commercial efforts.

***Other (Income) Expense***

Other (income) expense for the year ended December 31, 2021 primarily represents the gain of $1.4 million related to the forgiveness of the Paycheck Protection Program loan and the gain of $0.5 million recorded related to the termination of the joint venture in Australia. The increase in Interest and other income is primarily due rising interest rates.

***Benefit from Income Taxes***

The Benefit from income taxes of $0.4 million and $0.9 million for the years ended December 31, 2022 and 2021, respectively, primarily represent the sale of our state net operating losses and research and development tax credits under the State of New Jersey’s NOL Transfer Program.

**Liquidity and Capital Resources**

At December 31, 2022 our cash, cash equivalents, and restricted cash was $18.0 million compared to $34.7 million at December 31, 2021.

| | December 31, | |
|---|---|---|
| **(in thousands)** | **2022** | **2021** |
| **Net cash (used in) provided by** | | |
| Operating activities | $ (16,645) | $ (13,627) |
| Investing activities | $ — | $ 18,217 |
| Financing activities | $ — | $ 25,682 |

***Operating Activities***

Net cash used in operating activities was $16.6 million and $13.6 million for the years ended December 31, 2022 and 2021, respectively. This increase is primarily due to the increase in our net loss from operations.

***Investing Activities***

No cash was provided by investing activities during the year ended December 31, 2022. For the year ended December 31, 2021, net cash provided by investing activities was $18.2 million reflecting funds received from the maturity of marketable securities partially offset by our purchases of marketable securities.

***Financing Activities***

No cash was provided by financing activities during the year ended December 31, 2022. For the year ended December 31, 2021, net cash provided by financing activities was $25.7 million representing proceeds from the sale of our common stock.

***Liquidity Outlook***

In 2023, we expect to continue to incur substantial negative cash flows from operations. We intend to continue to make targeted investments in sales and marketing, as well as the next generation of our therapy delivery platform.

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 research and development activities, and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively.

We expect that a majority of our 2023 sales will be made pursuant to our qualifying contract under the Federal Supply Schedule, or FSS, as well as open market sales to individual facilities within the government channels. The FSS is scheduled to expire on January 15, 2024. We intend to request an extension of the FSS from the United States Department of Veteran Affairs, but there is no assurance the FSS agreement will be renewed, if at all, or at terms favorable to us. In addition, other possible 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.

Even if we are not required to curtail our activities sooner, our ability to execute our operating plan beyond the next 12 months from the date these financial statements are issued depends on our ability to increase revenue, control operating expenses and obtain additional funding from the sale of equity and or debt securities, a strategic transaction or otherwise. However, these alternatives may not be available to us on attractive terms, or at all. There is no assurance that we will generate sufficient cash flow and funding through our operating results or the sale of securities or from a strategic transaction or otherwise, raising substantial doubt about our ability to continue as a going concern within one year of the date these financial statements are issued.

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.

On February 13, 2023, we held a special meeting (the “Special Meeting”) of our stockholders. At the Special Meeting, our shareholders voted to approve an amendment to our Certificate of Incorporation as amended to effect a Reverse Stock Split of our ordinary shares (the “Reverse Stock Split”) at a ratio of not less than 1-for 5 and not more than 1-for-50, with such ratio and the implementation and timing of the Reverse Stock Split to be determined by the our board of directors in its sole discretion. Following the Special Meeting, our board of directors approved a 1-for-15 Reverse Stock Split and our Certificate of Incorporation, as amended was amended accordingly. The Reverse Stock Split became effective on February 15, 2023. The purpose of the Reverse Stock Split was to increase the per share trading price of our common stock on the Nasdaq Capital Market to regain compliance with the Bid Price Rule. On March 6, 2023, we received a letter from Nasdaq confirming that our common stock had regained compliance with the Bid Price Rule, and as a result, our common stock continues to trade on the Nasdaq Capital Market. If in the future we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the Bid Price Rule, Nasdaq may take steps to delist our common stock.

The Reverse Stock Split of our common stock had the effect of reducing the number of shares of common stock outstanding. There can be no assurance that the value and liquidity of our common stock will not be adversely affected by the Reverse Stock Split, which in turn could have a material adverse effect on our ability to raise the additional capital that we may require or increase the dilutive impact of any such financing.

**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, 2022.

Our exposure to market interest rate risk is confined to our cash and cash equivalents and restricted cash. 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 investigational sites, suppliers, customers, 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, 2022.

**Item 8. Financial Statements and Supplementary Data.**

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

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

None.

**Item 9A. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

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

As required by Rule 13a-15(b) of the Exchange Act, an evaluation as of December 31, 2022, 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, 2022, 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, 2022, 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, 2022 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, 2022 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

**Item 9B. Other Information**

*Annual Meeting Matters*

On March 3, 2023, our Board of Directors determined that the date of our 2023 Annual Meeting of Stockholders (the "2023 Annual Meeting") will be Monday, August 4, 2023. The 2023 Annual Meeting is expected to be a virtual-only meeting conducted via remote communications. The record date, time, and meeting website information for the 2023 Annual Meeting will be set forth in a proxy statement for the 2023 Annual Meeting, which will be filed prior to the 2023 Annual Meeting with the Securities and Exchange Commission.

Due to the fact that the meeting date for the 2023 Annual Meeting is advanced more than 30 days prior to the anniversary of our 2022 Annual Meeting which was held on December 2, 2022, we are providing the timelines for stockholder proposals and director nominations for the 2023 Annual Meeting.

- For stockholder proposals to be presented for inclusion in the Company's proxy materials for the 2023 Annual Meeting pursuant to Rule 14a-8 under the Securities Exchange Act of 1934 (the "Exchange Act"), they must be received not later than March 22, 2023;
- For stockholder proposals not for inclusion in the Company's proxy materials for the 2023 Annual Meeting, they must be received between April 6, 2023 and May 5, 2023;
- For director nominations by stockholders not soliciting proxies, they must be received between April 6, 2023 and May 5, 2023; and
- For director nominations by stockholders soliciting proxies, they must be received no later than June 5, 2023.

Any of the foregoing proposals or nominations must be delivered to, or mailed and received by, the Company's Corporate Secretary at the principal executive offices of the Company at 200 Forge Way, Suite 205, Rockaway, NJ 07866, in writing and in proper form, and must set forth the information required by the Company's amended and restated bylaws and applicable requirements under the Exchange Act rules.

*Elimination of Series A Preferred Stock.*

On March 6, 2023, we filed a certificate of elimination (the "Certificate of Elimination"), with the Secretary of State of the State of Delaware with respect to the Series A Preferred Stock, par value $0.001 per share ("Series A Preferred Stock"), that had been authorized and designated for issuance by our board on December 2, 2022. At the time of filing of the Certificate of Elimination, no shares of Series A Preferred Stock were outstanding. All previously issued shares of Series A Preferred Stock were redeemed pursuant to their terms on February 13, 2023. The Certificate of Elimination eliminated the previous designation of 80,000 shares of Series A Preferred Stock from our certificate of incorporation, and caused such previously designated shares to resume their status as authorized but unissued and non-designated shares of preferred stock.

**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 2023 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 2023 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 2023 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 2023 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 2023 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:


| | |
|---|---|
| Report of Independent Registered Public Accounting Firm (PCAOB ID # 688) | F-2 |
| Consolidated Balance Sheets | F-3 |
| Consolidated Statements of Operations | F-4 |
| Consolidated Statements of Comprehensive Loss | F-5 |
| Consolidated Statements of Equity | F-6 |
| Consolidated Statements of Cash Flows | F-7 |
| Notes to Consolidated Financial Statements | F-8 |


(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**

Not applicable.

| Exhibit Number | Description |
|---|---|
| 3.1*** | Certificate of Incorporation of electroCore, Inc. |
| 3.2***** | Amended and Restated Bylaws of electroCore, Inc. |
| 3.3******* | Certificate of Designation of the Series A Preferred Stock of the Company |
| 3.4* | Certificate of Elimination of the Series A Preferred Stock of the Company, dated March 3, 2023 |
| 3.5* | Certificate of Amendment to the Certificate of Incorporation, filed February 13, 2023 |
| 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
******* Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on December 27, 2022.
******** Incorporated by reference to the Company's Current Report on Form 8-K as filed with the Commission on February 14, 2023.
† 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 8, 2023 By: /s/ DANIEL S. GOLDBERGER

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

Date: March 8, 2023 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<br>**Peter Cuneo** | Chairman of the Board | March 8, 2023 |
| /s/ Julie A. Goldstein<br>**Julie A. Goldstein** | Director | March 8, 2023 |
| /s/ Daniel S. Goldberger<br>**Daniel S. Goldberger** | Director | March 8, 2023 |
| /s/ John Gandolfo<br>**John Gandolfo** | Director | March 8, 2023 |
| /s/ Joseph P. Errico<br>**Joseph P. Errico** | Director | March 8, 2023 |
| /s/ Thomas Patton<br>**Thomas Patton** | Director | March 8, 2023 |
| /s/ Thomas J. Errico, M.D.<br>**Thomas J. Errico, M.D.** | Director | March 8, 2023 |
| /s/ Patricia Wilber<br>**Patricia Wilber** | Director | March 8, 2023 |
| /s/ Trevor J. Moody<br>**Trevor J. Moody** | Director | March 8, 2023 |

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**


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|---|---|
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| Consolidated Balance Sheets as of December 31, 2022 and 2021 | F-3 |
| Consolidated Statements of Operations for the Years ended December 31, 2022 and 2021 | F-4 |
| Consolidated Statements of Comprehensive Loss for the Years ended December 31, 2022 and 2021 | F-5 |
| Consolidated Statements of Equity for the Years ended December 31, 2022 and 2021 | F-6 |
| Consolidated Statements of Cash Flows for the Years ended December 31, 2022 and 2021 | F-7 |
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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. (the “Company”) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss**,** equity, and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

**Explanatory Paragraph – Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 3, the Company has experienced significant losses and cash used in operations and expects to continue to incur net losses. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These 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 8, 2022

**ELECTROCORE, INC. AND SUBSIDIARIES**
**Consolidated Balance Sheets**
**(in thousands, except share data)**

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 17,712 | $ 34,689 |
| Restricted cash | 250 | — |
| Accounts receivable, net | 401 | 438 |
| Inventories, net | 1,982 | 1,361 |
| Prepaid expenses and other current assets | 828 | 1,053 |
| Total current assets | 21,173 | 37,541 |
| | | |
| Inventories, noncurrent | 2,194 | 3,941 |
| Property and equipment, net | 50 | 147 |
| Operating lease right of use assets, net | 565 | 613 |
| Other assets, net | 774 | 591 |
| Total assets | $ 24,756 | $ 42,833 |
| **Liabilities and Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,129 | $ 938 |
| Accrued expenses and other current liabilities | 4,842 | 4,486 |
| Current portion of operating lease liabilities | 74 | 61 |
| Total current liabilities | 7,045 | 5,485 |
| Noncurrent liabilities: | | |
| Operating lease liabilities, noncurrent | 625 | 700 |
| Total liabilities | 7,670 | 6,185 |
| Commitments and contingencies (see Note 13) | — | — |
| Mezzanine equity: | | |
| Preferred Stock, par value $0.001 per share; 10,000,000 shares authorized as of December 31, 2022 and December 31, 2021; 71,173 shares issued and outstanding at December 31, 2022 ($0.001 per share liquidation value) and 0 shares issued and outstanding at December 31, 2021 | — | — |
| Stockholders' equity: | | |
| Common Stock, par value $0.001 per share; 500,000,000 shares authorized as of both December 31, 2022 and 2021; 4,744,886 shares issued and outstanding at December 31, 2022, and 4,713,608 shares issued and outstanding at December 31, 2021 | 5 | 5 |
| Additional paid-in capital | 163,520 | 160,838 |
| Accumulated deficit | (146,370) | (124,208) |
| Accumulated other comprehensive (loss) income | (69) | 13 |
| Total equity | 17,086 | 36,648 |
| Total liabilities and equity | $ 24,756 | $ 42,833 |

See accompanying notes to the consolidated financial statements.

**ELECTROCORE, INC. AND SUBSIDIARIES**
**Consolidated Statements of Operations**
**(in thousands, except per share data)**

| | Years ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Net sales | $ 8,592 | $ 5,451 |
| Cost of goods sold | 1,616 | 1,385 |
| Gross profit | 6,976 | 4,066 |
| Operating expenses: | | |
| Research and development | 5,520 | 2,536 |
| Selling, general and administrative | 24,330 | 21,573 |
| Total operating expenses | 29,850 | 24,109 |
| Loss from operations | (22,874) | (20,043) |
| Other (income) expense: | | |
| Gain on extinguishment of debt | — | (1,422) |
| Gain on termination of joint venture | — | (549) |
| Interest and other income | (287) | (11) |
| Other expense | 6 | 8 |
| Total other income | (281) | (1,974) |
| Loss before income taxes | (22,593) | (18,069) |
| Benefit from income taxes | 431 | 851 |
| Net loss | (22,162) | (17,218) |
| Preferred stock dividend | — | — |
| Net loss available for common shareholders | $ (22,162) | $ (17,218) |
| Net loss per share of common stock - Basic and Diluted (see Note 9) | $ (4.69) | $ (4.36) |
| Weighted average common shares outstanding - Basic and Diluted (see Note 9) | 4,729 | 3,945 |

See accompanying notes to the consolidated financial statements.

**ELECTROCORE, INC. AND SUBSIDIARIES**
**Consolidated Statements of Comprehensive Loss**
**(in thousands)**

| | Years ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Net loss | $ (22,162) | $ (17,218) |
| Other comprehensive income (loss): | | |
| Foreign currency translation adjustment | (82) | 176 |
| Foreign currency translation adjustment - deconsolidation | — | 86 |
| Unrealized gain on marketable securities, net of taxes as applicable | — | 2 |
| Other comprehensive (loss) income | (82) | 264 |
| Preferred dividend | — | — |
| Comprehensive loss available to common shareholders | $ (22,244) | $ (16,954) |

See accompanying notes to consolidated financial statements.

**ELECTROCORE, INC. AND SUBSIDIARIES**
**Consolidated Statements of Equity**
**(in thousands)**

| | Mezzanine Equity | | Stockholders' Equity | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Preferred Stock | | Common Stock | | Additional paid-in capital | Accumulated deficit | Accumulated other comprehensive income (loss) | Total electroCore Inc., equity | Noncontrolling interest | Total equity |
| | Shares | Amount | Shares | Amount | | | | | | |
| Balances as of January 1, 2021 | — | — | 3,038 | 45 | 130,205 | (106,990) | (251) | 23,009 | 635 | 23,644 |
| Net loss | — | — | — | — | — | (17,218) | — | (17,218) | — | (17,218) |
| Other comprehensive income | — | — | — | — | — | — | 264 | 264 | — | 264 |
| Issuance of stock (see Note 8) | — | — | 1,563 | 24 | 25,658 | — | — | 25,682 | — | 25,682 |
| Issuance of stock to satisfy certain obligations (see Note 8) | — | — | 77 | 1 | 1,207 | — | — | 1,208 | — | 1,208 |
| Issuance of common stock in connection with employee stock plans, net of forfeitures | — | — | 25 | — | — | — | — | — | — | — |
| Settlement of accrued bonus | — | — | 11 | — | 400 | — | — | 400 | — | 400 |
| Share based compensation | — | — | — | 1 | 3,302 | — | — | 3,303 | — | 3,303 |
| Reverse stock split | — | — | — | (66) | 66 | — | — | — | — | — |
| Termination of joint venture | — | — | — | — | — | — | — | — | (635) | (635) |
| Balances as of January 1, 2022 | — | — | 4,714 | 5 | 160,838 | (124,208) | 13 | 36,648 | — | 36,648 |
| Net loss | — | — | — | — | — | (22,162) | — | (22,162) | — | (22,162) |
| Other comprehensive loss | — | — | — | — | — | — | (82) | (82) | — | (82) |
| Issuance of common stock in connection with employee stock plans, net of forfeitures | — | — | 31 | — | — | — | — | — | — | — |
| Dividend preferred (see Note 8) | 71 | — | — | — | — | — | — | — | — | — |
| Share based compensation | — | — | — | — | 2,682 | — | — | 2,682 | — | 2,682 |
| Balances as of December 31, 2022 | 71 | — | 4,745 | $ 5 | $ 163,520 | $ (146,370) | $ (69) | $ 17,086 | $ — | $ 17,086 |

See accompanying notes to the consolidated financial statements.

**ELECTROCORE, INC. AND SUBSIDIARIES**
**Consolidated Statements of Cash Flows**
**(in thousands)**

| | Year ended December 31, | |
|---|---|---|
| | **2022** | **2021** |
| Cash flows from operating activities: | | |
| Net loss | $ (22,162) | $ (17,218) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock based compensation | 2,682 | 3,302 |
| Depreciation and amortization | 548 | 382 |
| Amortization of marketable securities premium | — | 142 |
| Gain on extinguishment of debt | — | (1,422) |
| Gain on termination of joint venture | — | (549) |
| Gain on lease settlement | — | (57) |
| Increase in allowance for doubtful accounts | — | 49 |
| (Gain) loss on legal fee obligation settled with stock | — | (9) |
| Noncash lease expense | 48 | 55 |
| Inventory reserve charge | 196 | 70 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 37 | (217) |
| Inventories | 296 | 371 |
| Prepaid expenses and other assets | 225 | 716 |
| Accounts payable | 1,191 | 464 |
| Accrued expense and other current liabilities | 356 | 425 |
| Right of use operating lease assets | — | (151) |
| Operating lease liabilities | (62) | 20 |
| Net cash used in operating activities | (16,645) | (13,627) |
| Cash flows from investing activities: | | |
| Purchase of marketable securities | — | (5,083) |
| Proceeds from maturities of marketable securities | — | 23,300 |
| Net cash provided by investing activities | — | 18,217 |
| Cash flows from financing activities: | | |
| Proceeds from shares issued, net of related expenses | — | 25,682 |
| Net cash provided by financing activities | — | 25,682 |
| Effect of changes in exchange rates on cash and cash equivalents | (82) | 175 |
| Net (decrease) increase in cash and cash equivalents | (16,727) | 30,447 |
| Cash and cash equivalents – beginning of year | 34,689 | 4,242 |
| Cash and cash equivalents, and restricted cash – end of year | $ 17,962 | $ 34,689 |
| | | |
| Supplemental cash flows disclosures: | | |
| Proceeds from sale of state net operating losses | $ 445 | $ 877 |
| Income taxes paid | $ — | $ 39 |
| Interest paid | $ 6 | $ 10 |
| Supplemental schedule of noncash activity: | | |
| Insurance premium financing | $ 522 | $ 874 |
| Settlement of certain obligations through issuance of common stock | $ — | $ 1,275 |
| 2020 bonus paid in stock | $ — | $ 400 |

See accompanying notes to consolidated financial statements.

**Note 1. The Company**

electroCore, Inc. and its subsidiaries ("electroCore" or the "Company") is a commercial stage bioelectronic medicine and wellness company dedicated to improving health through its non-invasive vagus nerve stimulation ("nVNS") technology platform. The Company's focus is the commercialization of medical devices for the management and treatment of certain medical conditions and consumer product offerings utilizing nVNS to promote general wellbeing and human performance in the United States and select overseas markets.

electroCore, headquartered in Rockaway, NJ, has two wholly owned subsidiaries: electroCore UK Ltd and electroCore Germany GmbH. The Company has paused operations in Germany, with sales into the country and the rest of Europe being managed 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 10)

**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 the regulations of the Securities and Exchange Commission ("SEC").

At a special stockholders meeting held on February 13, 2023, the Company's stockholders approved an amendment to the Company's certificate of incorporation to effect of a reverse stock split of the Company's common stock at a ratio between 1-for-5 to 1-for-50 in order to achieve a minimum bid price of $1.00 per share for a minimum of 10 consecutive trading days, as required for continuing listing of the common stock on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). The board of directors authorized a 1-for-15 ratio for the reverse stock split, which became effective on February 15, 2023. The accompanying consolidated financial statements and notes to consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

***(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 subsequent consolidated financial statements. 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, estimated useful life of licensed product and cloud computing arrangements, 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. For the years ended December 31, 2022 and 2021, trade credits and discounts were immaterial.

***(e) Cash, Cash Equivalents and Restricted Cash***

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

The following table provides a reconciliation of cash, cash equivalents and restricted cash to the balance reflected on the Consolidated Statement of Cash Flow for the year ended December 31, 2022:

| (in thousands) | Year Ended December 31, 2022 |
|---|---|
| Cash and cash equivalents | $ 17,712 |
| Restricted cash | 250 |
| Total cash, cash equivalents and restricted cash | $ 17,962 |

***(f) Restricted Cash***

The Company's restricted cash consists of cash that the Company is contractually obligated to maintain in accordance with the terms of its corporate credit card arrangement with Citibank.

***(g) Concentration of Credit Risk***

Cash equivalents are financial instruments that potentially subject the Company to concentration of credit risk. As of December 31, 2022, the Company's cash equivalents 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, 2022, 95% of the Company's cash and cash equivalents were denominated in U.S. Dollars, the balance is subject to foreign exchange risk. 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.

***(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, 2022 and 2021, 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 goods 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 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. The accompanying Consolidated balance sheet as of December 31, 2022 includes a total of $1.2 million of such capitalized costs and the corresponding net amortized asset totaled $235,000.

***(m) Licensed Products***

The Company licenses a portion of its devices through its cash pay channels. The cost of these licensed devices is capitalized and included in Other Assets in the accompanying Consolidated Balance Sheets at December 31, 2022 and 2021, and is being recognized as cost of goods sold on the straight-line method over the estimated 12-36 month useful life of the devices. If certain licensed devices are returned and no longer meet quality specifications or the carrying amount of certain licensed devices are no longer deemed to be recoverable, the Company records a charge to cost of goods sold to write down such licensed devices to zero. During the year ended December 31, 2022, the Company recorded a charge to costs of goods sold of $239,000 related to such assets. The accompanying Consolidated balance sheet as of December 31, 2022 includes a total of $931,000 of capitalized licensed device costs and the corresponding net amortized assets totaled $538,000. Cash flows from licensed devices are included in Inventory in the accompanying Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021.

***(n) Impairment of Long-Lived Assets***

Long lived assets, such as property 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.

***(o) 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.

***(p) 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.

***(q) 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.

***(r) 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.

***(s) 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.

***(t) Prior year presentation***

Prior year presentation has been conformed to current year presentation.

***(u) Recently Adopted Accounting Standards***

There are no recent accounting pronouncements that are expected to have a material impact on the Company’s consolidated financial statements or related disclosures.

**Note 3. Significant Risks and Uncertainties**

*Going Concern*

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 medical devices and wellness products. The Company has never been profitable and has incurred net losses and cash used in operations in each year since its inception.

The United States Department of Veteran Affairs comprised 60.8 % of the Company's revenue during the year ended December 31, 2022. The Company expects that a majority of our 2023 sales will be made pursuant to its qualifying contract under the Federal Supply Schedule, or FSS, which was secured by the Company in December 2018, as well as open market sales to individual facilities within the government channels. The FSS is scheduled to expire on January 15, 2024. The Company intends to request an extension of the FSS from the United States Department of Veteran Affairs, but there is no assurance the FSS will be renewed, and if at all renewed at terms favorable to the Company. The Company's sales function in this channel is comprised of employees and independent contractors.

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. Due to the risks and uncertainties, the Company may need to reduce its activities significantly more than its current operating plan and cash flow projections assume in order to fund its operations beyond one year of the date the accompanying financial statements are issued. There can be no assurance that the Company will have sufficient cash flow and liquidity to fund its planned activities, which could force it to significantly reduce or curtail its activities and, ultimately, potentially cease operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern.

There is no assurance that the Company will generate sufficient funds through its operating results or financing activity raising substantial doubt about the Company’s ability to continue as a going concern within one year of the date of the accompanying financial statements are issued. The accompanying financial statements do not include any adjustment that might result from the outcome of this uncertainty.

*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. The VA/DoD and National Health Service were the Company’s sole customers accounting for 10% or more of total net sales during the years ended December 31, 2022 and 2021. The following table reflects the respective concentration as a percentage of the Company's net sales:

| | Years ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| **Revenue channel:** | | |
| VA/DoD | 60.8% | 59.8% |
| National Health Service | 15.1% | 24.1% |

During the years ended December 30, 2022 and 2021, one and two facilities accounted for more than 10% of total VA/DOD net sales, respectively. During the years ended December 31, 2022 and 2021, one facility accounted for more than 10% of net sales from the National Health Service.

*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 ongoing 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, 2022 and 2021 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 ongoing pandemic and containment measures, the emergence of new viral strains that are not responsive to the vaccines, 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, | |
|---|---|---|
| **(in thousands)** | **2022** | **2021** |
| **Product revenue** | | |
| United States | $ 6,974 | $ 3,940 |
| United Kingdom | 1,296 | 1,344 |
| Other | 183 | 167 |
| **License revenue** | | |
| Japan | 139 | — |
| Total Net Sales | $ 8,592 | $ 5,451 |

*Contract Balances*

The Company generally invoices the customer and recognizes revenue once its performance obligations are satisfied, at which point payment is unconditional. In March 2022, the Company entered into an agreement with Teijin Limited (Teijin), to license certain exclusive rights to its nVNS technology for commercialization in Japan for a range of primary headache disorders. Under the agreement, the Company received a non-refundable, upfront payment for the licenses and rights granted to Teijin. The Company began to recognize revenue for this upfront payment ratably over a period of one year commencing in the second quarter of 2022. As of December 31, 2022, the Company's Consolidated balance sheet included a contract liability related to the Teijin agreement in the amount of $152,000 which is included in Accrued expenses and other current liabilities. No further contracts with customers gave rise to contract assets or liabilities during the year ended December 31, 2022 and 2021. See Note 7 Accrued Expenses and other current liabilities.

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. Inventory**

As of December 31, 2022 and 2021, inventories consisted of the following:

| | December 31, | |
|---|---|---|
| **(in thousands)** | **2022** | **2021** |
| Raw materials | $ 944 | $ 769 |
| Work in process | 2,879 | 4,072 |
| Finished Goods | 353 | 461 |
| Total Inventory | 4,176 | 5,302 |
| Less: noncurrent inventory | 2,194 | 3,941 |
| Total current inventory | $ 1,982 | $ 1,361 |

As of December 31, 2022 and 2021, the Company reserved $668,000 and $821,000 respectively, for obsolete inventory. During the year ended December 31, 2022, the Company disposed of $110,000 of inventory which was previously reserved against. The Company records charges for obsolete inventory in cost of goods sold. As of December 31, 2022 and 2021, noncurrent inventory was comprised of approximately $0.1 million and $0.9 million of raw materials, respectively, and $2.1 million and $3.0 million of work in process, respectively. Inventory classified under the category Work in process consists of prefabricated assembled product.

**Note 6. Leases**

The Company accounts for leases in accordance with FASB ASU 2016-02, Leases (Topic 842), and its operating leases consist of 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, 2021. 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, 2021.

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 13,333 shares of its common stock. As of December 31, 2021, such payments were satisfied by the Company. The Company recorded a gain of $57,000 connection with the termination of the Agreement which is included in the accompanying Consolidated Statement of Operations for the year ended December 31, 2021 under the caption Operating expenses - Selling, general and administrative.

For the years ended December 31, 2022 and 2021, the Company recognized lease expense of $153,000 and $146,000, 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, | |
|---|---|---|
| **(in thousands)** | **2022** | **2021** |
| Operating leases: | | |
| Operating lease right of use assets | $ 565 | $ 613 |
| Operating lease liabilities: | | |
| Current portion of operating lease liabilities | 74 | 61 |
| Noncurrent operating lease liabilities | 625 | 700 |
| Total operating lease liabilities | $ 699 | $ 761 |
| Weighted average remaining lease term (in years) | 6.1 | 6.9 |
| Weighted average discount rate | 13.8% | 13.8% |

Future minimum lease payments under non-cancellable operating leases as of December 31, 2022:

| **Financial year (in thousands)** | |
|---|---|
| 2023 | $ 164 |
| 2024 | 168 |
| 2025 | 171 |
| 2026 | 161 |
| 2027 | 157 |
| 2028 and thereafter | 216 |
| Total future minimum lease payments | 1,037 |
| Less: Amounts representing interest | (338) |
| Total | $ 699 |

**Note 7. Accrued Expenses and Other Current Liabilities**

Accrued expenses as of December 31, 2022 and 2021 consisted of the following:

| | December 31, | |
|---|---|---|
| (in thousands) | 2022 | 2021 |
| Accrued professional fees | $ 524 | $ 468 |
| Accrued bonuses and incentive compensation | 2,042 | 1,849 |
| Accrued litigation legal fees expense | 1,001 | 605 |
| Accrued insurance expense | 264 | 499 |
| Accrued vacation and other employee related expenses | 534 | 455 |
| Accrued valued-added tax | 133 | 263 |
| Deferred Revenue | 152 | — |
| Other | 192 | 347 |
| | $ 4,842 | $ 4,486 |

*Finance and Security Agreements*

On July 5, 2022, the Company entered into a Commercial Insurance Premium Finance and Security Agreement (“the 2022 Agreement”). The 2022 Agreement provides for a single borrowing by the Company of approximately $783,000 with a nine-month term and an annual interest rate of 2.49%. The proceeds from this transaction were used to partially fund the premiums due under certain 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 $87,900 beginning in July 2022. As of December 31, 2022, the remaining balance under the Agreement was $264,000 and during the year ended December 31, 2022, the Company recognized $4,000 in interest expense.

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 of1.55%. 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 $499,000 and during the year ended December 31, 2021, the Company recognized $5,000 in interest expense.

*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 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 8. Stockholders' Equity**

All common stock share and per share data reflects the reverse stock split effective February 15, 2023, as described in Note 14. Subsequent Events, *Reverse stock split*.

*Dividend Preferred*

On December 2, 2022, the Company's board of directors declared a dividend of one one-thousandth of a share of Series A Preferred Stock, par value $0.001 per share ("Series A Preferred Stock"), for each outstanding share of the Company's common stock, to stockholders of record on December 19, 2022.

Each share of Series A Preferred Stock entitled the holder thereof to 1,000,000 votes per share, and each fraction of a share of Series A Preferred Stock had a ratable number of votes. Thus, each one-thousandth of a share of Series A Preferred Stock was entitled to 1,000 votes. The outstanding shares of Series A Preferred Stock voted together with the outstanding shares of the Company's common stock as a single class exclusively with respect to the proposal to adopt an amendment to the Company's Certificate of Incorporation, as amended, to reclassify the outstanding shares of the Company's Common Stock into a smaller number of shares of common stock at a ratio specified in or determined in accordance with the terms of such amendment (the "Reverse Stock Split").

The Company was not solely in control of the redemption of the shares of Series A Preferred Stock since the holders had the option of deciding whether to vote in respect of the above described Reverse Stock Split, which determined whether a given holder's shares of Series A Preferred Stock were redeemed in the Initial Redemption or the Subsequent Redemption. Since the redemption of the Series A Preferred Stock was not solely in the control of the Company, the shares of Series A Preferred Stock were classified within mezzanine equity in the Company's audited consolidated balance sheet. The shares of Series A Preferred Stock were measured at redemption value. The value of the shares of Series A Preferred Stock as of December 31, 2022 was $71. See Note 14. Subsequent Events, *Redemption and Elimination of Series A Preferred Stock.*

*Public Offering of CommonStock*

On July 2, 2021, the Company completed a public offering of 1,380,000 shares of its common stock at a purchase price of $15.00 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 63,492 shares of common stock, at a purchase price of $15.75 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 13,333 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 11,028 shares of its common stock as payment for certain executive incentive bonuses accrued in 2020.

*Stock Purchase Warrants*

The following table presents a summary of stock purchase warrants outstanding as of December 31, 2022:

| | Number of Warrants (in thousands) | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding, January 1, 2022 | 14 | $ 180.60 | 0.80 | $ — |
| Granted | — | — | | $ — |
| Exercised | — | — | | $ — |
| Expired | 13 | 138.05 | | $ — |
| Outstanding, December 31, 2022 | 1 | $ 229.50 | 2.0 | $ — |
| Exercisable, December 31, 2022 | 1 | $ 229.50 | 2.0 | $ — |

**Note 9. Net Loss Per Share**

All common stock share data reflects the reverse stock split effective February 15, 2023, as described in Note 14. Subsequent Events, *Reverse stock split*.

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, | |
|---|---|---|
| (in thousands) | 2022 | 2021 |
| Outstanding stock options | 440 | 342 |
| Nonvested restricted stock and unit awards | 127 | 72 |
| Stock purchase warrants | 1 | 14 |
| | 568 | 428 |

**Note 10. 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 $0.5 million in the accompanying Consolidated Statement of Operations for the year ended December 31, 2021 under the caption Gain on termination of joint venture.

**Note 11. Income Taxes**

The benefit for income taxes for the years ended December 31, 2022 and 2021 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:

| **(in thousands)** | **December 31, 2022** | **December 31, 2021** |
|---|---|---|
| Domestic | $ (21,518) | $ (16,679) |
| Foreign | (1,075) | (1,390) |
| Total | $ (22,593) | $ (18,069) |

The income tax (benefit)/expense from continuing operations contains the following components:

| (in thousands) | **December 31, 2022** | **December 31, 2021** |
|---|---|---|
| Federal | $ — | $ — |
| State | (449) | (870) |
| Foreign | 18 | 19 |
| Total current (benefit)/expense | (431) | (851) |
| | | |
| Total deferred | — | — |
| Total income tax (benefit)/expense | $ (431) | $ (851) |

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 $4.18 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, | |
|---|---|---|
| (in thousands) | 2022 | 2021 |
| Deferred tax assets | | |
| Net operating loss carryforwards | $ 29,854 | $ 26,924 |
| Accrued expenses | 257 | 579 |
| Intangibles | 1,720 | 469 |
| Fixed assets | 5 | (6) |
| Inventory | 165 | 216 |
| Allowance for bad debt | 3 | 3 |
| Charitable contributions | 10 | 11 |
| R&D credit | 422 | 430 |
| Deferred FICA Tax | — | 7 |
| Lease liabilities | 172 | 200 |
| Stock compensation | 4,744 | 4,430 |
| Deferred tax assets | 37,352 | 33,263 |
| Less valuation allowance | (37,046) | (32,868) |
| Total deferred tax assets | 306 | 395 |
| Prepaid expenses | (167) | (234) |
| Right of use asset | (139) | (161) |
| Total deferred tax liabilities | (306) | (395) |
| Deferred tax assets, net | $ — | $ — |

A reconciliation of the income tax expense (benefit) computed at the U.S. federal statutory income tax rate of 21% and the reported income tax expense (benefit) for the years ended December 31, 2022 and 2021 is as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Statutory rate | (21.0)% | (21.0)% |
| State tax expected (recovery), net of federal benefit | (7.3)% | 5.7% |
| State tax rate change | 9.5% | —% |
| Stock compensation | (0.2)% | (5.7)% |
| State tax NOL sale | (1.6)% | (3.8)% |
| Nondeductible expenses | 0.2% | 2.1% |
| PPP loan forgiveness | —% | (1.7)% |
| Unrealized gain from termination of joint venture | —% | (1.8)% |
| Change in valuation allowance for deferred tax assets | 18.5% | 21.5% |
| Income tax benefit | (1.9)% | (4.7)% |

As of December 31, 2022 and 2021, the Company had accumulated Federal net operating losses totaling $119.7 million and $103.9 million, respectively. Also, as of December 31, 2022 and 2021, the Company had state post-apportioned net operating losses totaling $47.0 million and $40.5 million, respectively. The net operating losses 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 $3.4 million and $3.6 million for the years ended December 31, 2022 and 2021, respectively, 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, 2022 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 $445,000 of income tax benefit, net of transaction costs. The Company recognized $877,000 of income tax benefit from the sale of New Jersey carry forwards in 2021. There can be no assurance as to the continuation or magnitude of this program in the future.

As of December 31, 2022, the Company had Federal and NJ research and development credits of $283,000 and $192,000 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’s U.S. federal and state net operating losses have occurred since inception in 2018 and as such, tax years subject to potential tax examinations could apply from that date because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. The Company currently has no tax years under examination.

As of December 31, 2022, the Company does not have an accrual relating to uncertain tax positions. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. It is not anticipated that unrecognized tax benefits would significantly increase or decrease within 12 months of the reporting date.

**Note 12. Stock Based Compensation**

All common stock share and per share data reflects the reverse stock split effective February 15, 2023, as described in Note 14. Subsequent Events, *Reverse stock split*.

On June 21, 2018, the Company adopted the 2018 Omnibus Equity Incentive Plan ("Plan"). This plan reserved 0.4 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 3.0 million shares, and a maximum of 2.7 million shares pursuant to the exercise of stock options. Effective January 1, 2023, the number of shares reserved under the Plan was increased by 0.2 million to approximately 0.9 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, 2022 and 2021. Total unrecognized compensation cost related to equity awards as of December 31, 2022 was $2.8 million and is expected to be recognized over the next 1.5 years.

| (in thousands) | Year ended December 31, 2022 | 2021 |
|---|---|---|
| Selling, general and administrative | $ 2,319 | $ 2,902 |
| Research and development | 335 | 332 |
| Cost of goods sold | 28 | 68 |
| Total expense | $ 2,682 | $ 3,302 |

The following table presents a summary of stock option award activity during the year ended December 31, 2022:

| | Number of Options (in thousands) | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding, January 1, 2022 | 342 | $ 69.15 | 8.0 | $ — |
| Granted | 105 | 10.05 | | $ — |
| Exercised | — | — | | $ — |
| Cancelled | (7) | 30.00 | | $ — |
| Outstanding, December 31, 2022 | 440 | $ 55.65 | 7.5 | $ — |
| Exercisable, December 31, 2022 | 230 | $ 88.80 | 6.6 | $ — |

The intrinsic value is calculated as the difference between the fair market value at December 31, 2022 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, 2022:

| Exercise Price | Options Outstanding (in thousands) | Options Outstanding Weighted Average Remaining Contractual Life (Years) | Options Exercisable (in thousands) |
|---|---|---|---|
| $0.01 - $37.50 | 328 | 7.9 | 135 |
| $37.65 - $112.80 | 43 | 7.1 | 26 |
| $112.95 - $225.00 | 69 | 5.5 | 69 |

The following table presents a summary of restricted and deferred stock unit (“Unit” or "Units") activity during the year ended December 31, 2022:

| | Number of Shares (in thousands) | Weighted Average Grant Date Fair Value |
|---|---|---|
| Nonvested, January 1, 2022 | 70 | $ 24.90 |
| Granted | 89 | 5.85 |
| Vested | (31) | 23.70 |
| Cancelled | (1) | 30.90 |
| Nonvested, December 31, 2022 | 127 | $ 11.85 |

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. Beginning in December 2022, the Company began incorporating its historical common stock volatility at a weighting of 50% of the total composite volatility rate. During 2023, the Company will continue to evaluate the volatility rate used to value stock options. 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:

| | 2022 | 2021 |
|---|---|---|
| Fair value at grant date | $ 7.20 | $ 19.80 |
| Expected volatility | 90.6% | 80.2% |
| Risk-free interest rate | 2.1% | 0.7% |
| Expected holding period, in years | 5.8 | 6.0 |
| Dividend yield | — | — |

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

**Note 13. Commitments and Contingencies**

***Stockholders Litigation***

On July 8, 2019, and August 1, 2019, purported stockholders of the Company served putative class action lawsuits in the Superior Court of New Jersey for Somerset County, captioned *Paul Kuehl vs. electroCore, Inc., et al.*, Docket No. SOM-L 000876-19 and *Shirley Stone vs. electroCore, Inc., et al.*, Docket No. SOM-L 001007-19, respectively. In addition to the Company, the defendants include present and past directors and officers, Evercore Group L.L.C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for its IPO; and two of the Company's stockholders. On August 15, 2019, the Superior Court entered an order consolidating the *Kuehl* and *Stone* actions, which 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 has been 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 forum selection clause in our certificate of incorporation's. 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 the supplemental motion to dismiss based on the federal forum selection clause with prejudice and granted the original motion to dismiss without prejudice. On January 27, 2022, the plaintiffs filed a notice of appeal to the Appellate Division. On April 15, 2022, the plantiffs filed their appeal brief. The brief of defendant-appellees was filed on May 16, 2022. The appeal is fully briefed. Oral argument is scheduled for April 19, 2023.

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

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 in the *Turnofsky* case. The defendants have moved to dismiss. Briefing on the motion was complete on January 7, 2022. On July 5, 2022, the case was reassigned to Judge Zahid N. Quraishi, who has ordered that he will consider the pending motion to dismiss in due course. Argument of the motion has not yet been scheduled.

On March 4, 2021, purported stockholder Richard Maltz 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 Erin Yuson brought a purported stockholder derivative action in the United States District Court for the District of New Jersey. The action is captioned *Erin 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 plaintiffs 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. These cases also have been re-assigned to Judge Quraishi.

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 is subject to various claims, complaints and legal actions in the normal course of business from time to time. The Company is not aware of any further currently pending litigation for which it believes the outcome could have a material adverse effect on its operations or financial position. The Company expenses associated legal fees including those relating to the stockholder litigation described in this Note 13 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 no material purchase obligations as of December 31, 2022.

**Note 14. Subsequent events**

*Reverse stock split*

On February 13, 2023, the Company held a special meeting (the "Special Meeting") of stockholders of the Company. At the Special Meeting, the Company's shareholders voted to approve an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock (the "Reverse Stock Split") at a ratio between 1-for-5 and 1-for-50.

Following the Special Meeting, the board of directors of the Company approved a 1-for-15 Reverse Stock Split. The Reverse Stock Split became effective on February 15, 2023.

Upon the effectiveness of the Reverse Stock Split, every 15 shares of common stock were automatically combined and converted into one share of common stock. Appropriate adjustments were also made to all outstanding derivative securities of the Company, including all outstanding equity awards and warrants.

No fractional shares were issued in connection with the Reverse Stock Split. Instead, all fractional shares received a cash payment based on the closing sales price on the Nasdaq Capital Market of the Company's common stock on February 14, 2023.

*Redemption and Elimination of Series A Preferred Stock*

All shares of Series A Preferred Stock that were not present in person or by proxy as of immediately prior to the opening of the polls at the Special Meeting were automatically redeemed by the Company (the "Initial Redemption"). Any outstanding shares of Series A Preferred Stock that had not been so redeemed were redeemed automatically upon the approval at the Special Meeting of the Reverse Stock Split (the "Subsequent Redemption"). Each share of Series A Preferred Stock redeemed was entitled to receive an amount equal to $0.01 in cash for each 10 whole shares of Series A Preferred Stock owned immediately prior to the Redemption.

On March 6, 2023, the Company filed a certificate of elimination (the "Certificate of Elimination"), with the Secretary of State of the State of Delaware with respect to the Series A Preferred Stock. The Certificate of Elimination (i) eliminated the previous designation of 80,000 shares of Series A Preferred Stock from the Company's Certificate of Incorporation, none of which were outstanding at the time of the filing of the Certificate of Elimination, and (ii) caused such shares of Series A Preferred Stock to resume their status as authorized but unissued and non-designated shares of preferred stock.

*Sales of net operating losses*

The Company may be eligible, from time to time, to receive cash from the sale of its net operating losses under New Jersey's Department of the Treasury - Division of Taxation NOL Transfer Program. On January 10, 2023, the Company received a net cash amount of approximately $211,000 from the sale of its New Jersey state net operating losses.

**Exhibit 3.4**

**CERTIFICATE OF ELIMINATION**
**OF**
**CERTIFICATE OF DESIGNATION**
**OF**
**SERIES A PREFERRED STOCK**
**OF**
**ELECTROCORE, INC.**

Pursuant to Sections 103 and 151(g) of the Delaware General Corporation Law

electrocCore, Inc. (the "Corporation"), pursuant to the provisions of the Delaware General Corporation Law , does hereby certify and set forth as follows:

**First:** On March 3, 2023, the Board of Directors of the Corporation approved a resolution to eliminate the Corporation's Certificate of Designation, Preferences and Rights (the "Certificate of Designation") of the Series A Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), that was filed with the Secretary of State of the State of Delaware on December 6, 2022;

**Second:** No shares of Series A Preferred Stock are issued and outstanding as of the date hereof, and the Corporation will not issue any additional shares of Series A Preferred Stock pursuant to the Certificate of Designation of the Series A Preferred Stock;

**Third:** The Certificate of Designation of the Series A Preferred Stock is hereby eliminated; and

**Fourth:** This Certificate of Elimination shall be effective as of 5:00 p.m. eastern time on March 6, 2023.

**Fifth:** Upon effectiveness of the filing of this Certificate of Elimination, the shares that were previously designated under the Certificate of Designation as Series A Preferred Stock shall resume the status of authorized but unissued shares of preferred stock of the Corporation, issuable from time to time, in one or more series, pursuant to Section 4(b) of the Corporation's Certificate of Incorporation, as amended.

**IN WITNESS WHEREOF**, the Corporation has caused this Certificate of Elimination of Certificate of Designation of Series A Preferred Stock to be signed by a duly authorized officer of the Corporation this 6th day of March, 2023.

**ELECTROCORE, INC.**

/s/ *Brian M. Posner*
Name: Brian M. Posner
Title: Chief Financial Officer

**Exhibit 3.5**

**CERTIFICATE OF AMENDMENT**
**OF**
**CERTIFICATE OF INCORPORATION**
**OF**
**ELECTROCORE, INC.**

electroCore, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), does hereby certify as follows:

1. The name of the Corporation is electroCore, Inc.

2. The Certificate of Incorporation of the Corporation is amended by adding the following new paragraph to the end of Article IV, Section C:

6. Upon the filing and effectiveness (the "***Effective Time***") of this amendment to the Corporation's Certificate of Incorporation, as amended, pursuant to the Delaware General Corporation Law, each fifteen (15) shares of the Common Stock issued immediately prior to the Effective Time (the "***Old Common Stock***") shall be reclassified and combined into one (1) validly issued, fully paid and non-assessable share of the Corporation's Common Stock, $0.001 par value per share (the "***New Common Stock***"), without any action by the holder thereof (the "***Reverse Stock Split***"). No fractional shares of New Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Effective Time of a book entry position which formerly represented shares of Old Common Stock that were issued and outstanding immediately prior to the Effective Time, any person who would otherwise be entitled to a fractional share of New Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of New Common Stock to which such holder would otherwise be entitled multiplied by the closing price per share of the New Common Stock on The Nasdaq Stock Market LLC at the close of business on the date prior to the Effective Time. Each book entry position that immediately prior to the Effective Time represented shares of Old Common Stock shall thereafter represent that number of shares of New Common Stock into which the shares of Old Common Stock represented by such book entry position shall have been reclassified and combined, subject to the elimination of fractional shares set forth above.

3. This Certificate of Amendment has been duly adopted by the Board of Directors and stockholders of the Corporation in accordance with Section 242 of the General Corporation Law of the State of Delaware.

4. This Certificate of Amendment shall become effective as of 12:01 a.m., Eastern Time on February 15, 2023.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be duly executed in its corporate name as of the 13th day of February, 2023.

By: */s/ Daniel S. Goldberger*
Daniel S. Goldberger
Chief Executive Officer

**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, 2023, there were 4,742,450 shares of common stock outstanding. The Company also has 10 million authorized shares of preferred stock, par value $0.001 per share, which may be issued in one or more series as may be designated by our Board of Directors. No such shares of preferred stock are issued or outstanding as of the date of this Annual Report on Form 10-K.

## 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.

**Series A Preferred Stock**

On March 6, 2023, the Company filed a certificate of elimination (the "Certificate of Elimination"), with the Secretary of State of the State of Delaware with respect to the Series A Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"). The Certificate of Elimination (i) eliminated the previous designation of 80,000 shares of Series A Preferred Stock from the Company's Certificate of Incorporation, none of which were outstanding at the time of the filing of such Certificate of Elimination, and (ii) caused such shares of Series A Preferred Stock to resume their status as authorized but unissued and non-designated shares of Preferred Stock.

**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**[1]. 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.

[1] Solely with respect to the annual equity award made on December 2, 2022 for each of the six continuing non-employee directors, the Board approved a one-time cap on the number of shares issuable pursuant to such awards as follows: (i) 215,022 RSUs or DSUs per director, and (ii) 322,534 stock options for the Chairman of the Board.

(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, 333-254171, and 333-263675) of our report dated March 8, 2023, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of electroCore, Inc. and Subsidiaries as of December 31, 2022 and 2021 and for the years ended December 31, 2022 and 2021, which report is included in this Annual Report on Form 10-K of electroCore, Inc. for the year ended December 31, 2022.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 8, 2023

**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 8, 2023

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 8, 2023

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, 2022 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 8, 2023

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, 2022 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 8, 2023

By: /s/ BRIAN M. POSNER

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