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PROSPECTUS SUPPLEMENT
(To Prospectus dated September 5, 2019)

Up to $25,000,000 of Common Stock and
692,514 Shares of Common Stock

This prospectus supplement relates to the issuance and sale of up to $25,000,000 of shares of our common stock, $0.001 par value per share (the "Common Stock"), that we may issue to Lincoln Park Capital Fund, LLC ("Lincoln Park") from time to time under a Purchase Agreement that we entered into with Lincoln Park on March 27, 2020 (the "Purchase Agreement"), and up to an additional 692,514 shares of Common Stock issuable to Lincoln Park as a commitment fee for entering into the Purchase Agreement (the "Commitment Shares").

This prospectus supplement and the accompanying prospectus also cover the resale of these shares by Lincoln Park to the public.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "ECOR." On March 26, 2020, the last reported sales price of our common stock on the Nasdaq Global Select Market was $0.465 per share.

Investing in our common stock involves risks. See "Risk Factors" beginning on page S-28 of this prospectus supplement, page 4 of the accompanying prospectus and the documents incorporated by reference into this prospectus supplement.

Neither the Securities and Exchange Commission nor any securities commission of any state or other jurisdiction has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is March 30, 2020.

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We have not authorized anyone to provide you with information different than that which is contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. We are not making an offer to sell or soliciting offers to buy these securities in any jurisdiction where the offer, solicitation or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any related free writing prospectus, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any related free writing prospectus, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement and the accompanying prospectus titled "Where You Can Find More Information" and "Information Incorporated by Reference."

The distribution of this prospectus supplement and the accompanying prospectus or any free writing prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus or any free writing prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus or any free writing prospectus outside the United States.

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated September 5, 2019, including the documents incorporated by reference therein, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission (the "SEC") before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement. You should assume that the information contained in this prospectus supplement is accurate as of the date on the front cover of this prospectus supplement only and that any information we have incorporated by reference or included in the accompanying prospectus is accurate only as of the date given in the document incorporated by reference or as of the date of the prospectus, as applicable, regardless of the time of delivery of this prospectus supplement or the accompanying prospectus or any sale of our common stock. Our business, financial condition, liquidity, results of operations and prospects may have changed since that date.

In this prospectus supplement, 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, and its subsidiaries and affiliate.

The electroCore logo, gammaCore, gammaCore Sapphire and other trademarks of electroCore, Inc. appearing in this prospectus are the property of electroCore, Inc. All other trademarks, service marks and trade names in this prospectus supplement are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks used in this prospectus supplement.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and certain information incorporated herein by reference contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this prospectus supplement that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements.

Factors that could cause or contribute to such differences include, but are not limited to, those included in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein, as well as those contained in our Annual Report on Form 10-K for the year ended December 31, 2018, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, and our Current Reports on Form 8-K, including those described under "Risk Factors" herein and therein. Other risks may be described from time to time in our filings made under the securities laws, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. There may be additional risks, uncertainties and factors that we do not currently view as material or that are not known. The forward-looking statements contained in this document are made only as of the date of this document. Except as required by law, we undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, as well as those described elsewhere in this prospectus supplement and accompanying prospectus, and other factors that we may publicly disclose from time to time. Furthermore, such forward-looking statements speak only as of the date made.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information contained elsewhere in this prospectus supplement. This summary does not contain all the information that you should consider before investing in our common stock. You should carefully read the entire prospectus supplement and accompany prospectus, including "Risk Factors", and the information incorporated by reference into this prospectus supplement, before making an investment decision.

Overview

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

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

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

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

Our Corporate Information

Our principal executive offices are located at 150 Allen Road, Suite 201, Basking Ridge, New Jersey 07920. Our telephone number is (973) 290-0097 and our website address is www.electrocore.com. We have included our website address in this prospectus supplement as an inactive textual reference only. The information available on or accessible through our website does not constitute a part of this prospectus supplement or the accompanying prospectus and should not be relied upon. Our common stock is listed on the Nasdaq Global Select Market under the symbol "ECOR."

The Offering

The following summary contains the principal terms of this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus supplement and the accompanying prospectus.

Issuer	electroCore, Inc.
Common stock offered by us(1)	Up to $25,000,000 of shares of Common Stock we may sell to Lincoln Park from time to time, at our sole discretion, in accordance with the Purchase Agreement; and up to 692,514 Commitment Shares.
Common Stock outstanding immediately after the offering(2)	Up to 35,951,477 shares of Common Stock, assuming an average sales price of $0.465 per share (the last reported sales price of our Common Stock on the Nasdaq Global Select Market on March 26, 2020) for the $25,000,000 of shares of Common Stock we may sell to Lincoln Park from time to time, including up to 692,514 Commitment Shares. The actual number of shares issued and outstanding will vary depending on the sale prices of shares sold to Lincoln Park in this offering, but unless sold in accordance with Nasdaq rules, the number of shares issued will not be greater than 5,991,912, representing 19.99% of the 29,959,565 shares of Common Stock outstanding on the date of the Purchase Agreement.
Use of Proceeds	We intend to use the net proceeds from this offering for working capital and general corporate purposes.
Listing	Our common stock is listed on the Nasdaq Global Select Market under the symbol “ECOR.”
Risk Factors	See “Risk Factors” included in this prospectus supplement, the accompanying prospectus and otherwise incorporated by reference in this prospectus supplement and the accompanying prospectus for a description of factors that you should consider before purchasing shares of our common stock.

(1) The Purchase Agreement prohibits us from issuing or selling to Lincoln Park under the Purchase Agreement (i) in excess of 5,991,912 shares of our Common Stock (the “Exchange Cap”), unless we obtain stockholder approval or the average price of all applicable sales of our Common Stock to Lincoln Park under the Purchase Agreement is equal to or greater than $0.4719 (the “Minimum Price”) and (ii) any shares of our Common Stock if those shares, when aggregated with all other shares of our Common Stock then beneficially owned by Lincoln Park and its affiliates, would exceed 4.99% of the then total outstanding shares of our Common Stock (the “Beneficial Ownership Cap”).
(2) The number of shares of our common stock to be outstanding immediately after this offering is based on 29,959,565 shares outstanding as of March 26, 2020.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise of outstanding options or warrants to purchase common stock, and no settlement of restricted stock units, in each case since September 30, 2019.

Agreement with Lincoln Park Capital Fund, LLC

On March 27, 2020, we entered into a Purchase Agreement and a Registration Rights Agreement with Lincoln Park, pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, we have the right to sell to Lincoln Park up to $25,000,000 of shares of our Common Stock at our discretion as described below.

As consideration for entering into the Purchase Agreement, we issued 461,676 shares of our Common Stock to Lincoln Park as initial Commitment Shares. We will also issue an additional 230,838 shares of our Common Stock as additional Commitment Shares based on a pro-rata percentage of the first $5,000,000 of shares issued to Lincoln Park under the Purchase Agreement. We will not receive any cash proceeds from the issuance of any Commitment Shares.

We are filing this prospectus supplement pursuant to the terms of the Registration Rights Agreement to cover the offer and sale of (i) up to $25,000,000 of shares of our Common Stock, subject to the conditions and limitations in the Purchase Agreement, and (ii) up to 692,514 Commitment Shares.

Over the 36-month term of the Purchase Agreement, up to an aggregate amount of $25,000,000 (subject to certain limitations) of shares of Common Stock, we have the right, but not the obligation, from time to time, in our sole discretion and subject to certain conditions, to direct Lincoln Park to purchase up to 200,000 shares subject to certain increases in accordance with the terms of the Purchase Agreement (the “Regular Purchase Share Limit”) of our Common Stock (each such purchase, a “Regular Purchase”). In any case, Lincoln Park’s maximum obligation under any single Regular Purchase will not exceed $1,000,000, unless we mutually agree to increase the maximum amount of such Regular Purchase. The purchase price (“Purchase Price”) for shares of Common Stock to be purchased by Lincoln Park under a Regular Purchase will be the equal to the lower of (in each case, subject to the adjustments described in the Purchase Agreement) (i) the lowest sale price for our Common Stock on the applicable purchase date, and (ii) the arithmetic average of the three lowest sale prices for our Common Stock during the ten trading days ending on the business day immediately preceding the purchase date.

If we direct Lincoln Park to purchase the maximum number of shares of Common Stock that we then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, we may direct Lincoln Park to make an “accelerated purchase” of an additional amount of Common Stock that may not exceed the lesser of (i) 300% of the number of shares purchased pursuant to the corresponding Regular Purchase, or (ii) 30% of the total number of shares of our Common Stock traded during a specified period on the applicable purchase date as set forth in the Purchase Agreement. The purchase price for such shares will be the lesser of (i) the closing sale price for the Common Stock on the date of sale, or (ii) 97% of the volume weighted average price of the Common Stock over a certain portion of the date of sale as set forth in the Purchase Agreement.

Under certain circumstances and in accordance with the Purchase Agreement, provided that we have directed Lincoln Park to make an accelerated purchase, on the following business day we may direct Lincoln Park to make an “additional accelerated purchase” on the following business day on the same terms as applicable to an accelerated purchase. Under certain circumstances and in accordance with the Purchase Agreement, the Company may direct Lincoln Park to purchase shares in multiple accelerated purchases or additional accelerated purchases on the same trading day.

At any time following the 30-day anniversary of our eligibility to sell shares of Common Stock to Lincoln Park pursuant to the Purchase Agreement, we have the option to direct Lincoln Park to purchase up to $4,000,000 of Common Stock at a price that is equal to 95% of the Purchase Price, in a maximum of four incremental purchases of up to $1,000,000 each.

We will control the timing and amount of any sales of our Common Stock to Lincoln Park. There is no upper limit on the price per share that Lincoln Park must pay for our Common Stock under the Purchase Agreement.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of Common Stock if those shares, when aggregated with all other shares of our Common Stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates exceeding the Beneficial Ownership Cap at any single point in time.

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

Events of default under the Purchase Agreement generally include the following:

- a lapse in the effectiveness of the registration statement on Form S-3 or the unavailability of this prospectus supplement for selling shares to Lincoln Park, in each case lasting for ten consecutive business days or thirty business days in any 365-day period;
- the suspension of our Common Stock from trading on the Nasdaq Global Select Market for a period of one business day;
- the delisting of our Common Stock from Nasdaq Global Select Market; provided, however, that our Common Stock is not immediately thereafter trading on the New York Stock Exchange, the Nasdaq Capital Market, the Nasdaq Global Market, the NYSE American, the NYSE Arca, the OTC Bulletin Board or OTC Markets (or nationally recognized successor to any of the foregoing);
- the failure for any reason by the transfer agent to issue the securities offered hereby to Lincoln Park within three business days after the applicable date on which Lincoln Park is entitled to receive such securities;
- any breach of the representations and warranties or covenants contained in the Purchase Agreement or any related agreements with Lincoln Park if such breach could have a material adverse effect and such breach is not cured within five trading days;
- our participation in insolvency or bankruptcy proceedings by or against us, as more fully described in the Purchase Agreement;
- if at any time we are not eligible to transfer our Common Stock electronically via Deposit/Withdrawal at Custodian, or any similar program hereafter adopted by The Depository Trust Company performing substantially the same function; or
- the Exchange Cap is reached.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside the control of Lincoln Park, shares of our Common Stock cannot be sold by us or purchased by Lincoln Park under the terms of the Purchase Agreement.

We may at any time, in our sole discretion, terminate the Purchase Agreement without fee, penalty or cost, upon one trading day's written notice. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

The above description of the Purchase Agreement is qualified in its entirety by reference to the Purchase Agreement, which has been filed with the SEC and is incorporated by reference into this prospectus supplement.

Amount of Potential Proceeds to be Received under the Purchase Agreement

Under the Purchase Agreement, we may sell shares of Common Stock having an aggregate offering price of up to $25,000,000 to Lincoln Park from time to time. The number of shares ultimately offered for sale to Lincoln Park in this offering is dependent upon the number of shares we elect to sell to Lincoln Park under the Purchase Agreement. The following table sets forth the amount of proceeds we would receive from Lincoln Park from the sale of shares at varying purchase prices:

Assumed Average Purchase Price	Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price(1)(2)	Percentage of Outstanding Shares After Giving Effect to the Additional Purchased Shares Issued to Lincoln Park(3)	Proceeds from the Sale of Shares Under the Purchase Agreement Registered in this Offering
$ 0.30	5,454,687	15.17%	$ 1,636,406
$ 0.465 (4)	5,414,008	15.06%	$ 2,517,514
$ 1.00	25,000,000	44.92%	$ 25,000,000
$ 3.00	8,333,333	21.38%	$ 25,000,000
$ 5.00	5,000,000	14.02%	$ 25,000,000

(1) Includes the total number of Purchase Shares (but not Commitment Shares) that we would have sold under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column, up to the aggregate purchase price of $25,000,000.

(2) The Purchase Agreement prohibits us from issuing or selling to Lincoln Park under the Purchase Agreement (i) shares of our Common Stock in excess of the Exchange Cap, unless we obtain stockholder approval or the average price of all applicable sales of our Common Stock to Lincoln Park under the Purchase Agreement is equal to or greater than the Minimum Price and (ii) any shares of our Common Stock if those shares, when aggregated with all other shares of our Common Stock then beneficially owned by Lincoln Park and its affiliates, would exceed the Beneficial Ownership Cap.

(3) The denominator is based on 29,959,565 shares outstanding as of March 26, 2020, the 461,676 shares previously issued to Lincoln Park and the number of shares set forth in the adjacent column that we would have sold to Lincoln Park. The numerator is based on the additional number of shares which we may issue to Lincoln Park under the Purchase Agreement, which are the subject of this offering at the corresponding assumed purchase price set forth in the adjacent column and the 461,676 shares previously issued to Lincoln Park.

(4) The closing sale price of the Common Stock on March 26, 2020.

BUSINESS OVERVIEW

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

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

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

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

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

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

Background of VNS

The vagus nerve is the largest and most extensive cranial nerve, connecting the brainstem to nearly every organ in the chest and abdomen. Modulating the firing rate of the fibers within the vagus nerve can trigger the release of neurotransmitters, both in the central and peripheral nervous systems, affecting how the brain and peripheral organs function. In the central nervous system, VNS activates areas of the brainstem that release norepinephrine, acetylcholine, serotonin, gamma aminobutvric acid and other important biochemicals. The release of these substances, which have been the targets of numerous pharmaceutical agents, can be used to treat multiple conditions, including epilepsy, depression and headache.

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

Our Therapy Delivery Platform

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

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

Competitive Strengths

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

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

- ***Our non-invasive therapy unlocks the long-held potential of VNS.*** VNS therapy can, for the first time, be delivered safely and comfortably through the skin using gammaCore. This eliminates the need for costly, invasive surgery that requires the implantation of an expensive medical device. VNS therapy is no longer reserved for the most refractory patients.
- ***Commercial arrangements in the United States and the United Kingdom.*** In the United States, we expect that a majority of our 2020 sales of gammaCore will be made pursuant to our qualifying contract under the Federal Supply Schedule, or FSS, which was secured by us in December 2018, and open market sales to individual facilities. We have access to workers compensation and personal injury patients through our distribution agreement with Doctor's Medical, LLC announced in August 2019. In the United Kingdom, the NHS, awarded gammaCore a place on the Innovation Technology Payment program for the treatment of refractory cluster headache, a reimbursement pathway that opened in April 2019. Furthermore, in December 2019 NICE published a Medical Technology Guidance document recommending the use of gammaCore for CH within the NHS. Together, we believe that these independent validations offer the potential for us to generate revenue from the treatment of CH.

- ***Broad intellectual property protection.*** Among our key issued patents, we have coverage on using our high-frequency burst electrical signal for treating certain medical conditions until 2031, the low-pass filtering of that signal to ensure safe and comfortable transmission through the skin until 2031, the non-invasive treatment of headache conditions until 2029, and the remote network-enabled communication for the delivery of neuromodulation therapy for a broad range of medical conditions until 2033.
- ***Highly experienced management team***. Our management team includes a diverse group of executives with significant experience in senior positions in the medical device and pharmaceutical industries. Our team's experience in clinical development, regulatory affairs, reimbursement and sales and marketing, allow us to pursue our strategy and growth plans.

Our Strategy

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

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

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

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

Recent Developments

On March 26, 2020, our board of directors (the "Board") appointed three new members, effective April 2, 2020. The newly appointed board members are Peter Cuneo, John Gandolfo and Thomas Patton (the "New Directors"). Each of the New Directors was appointed to the Audit Committee of the Board, and Mr. Cuneo was also appointed to the Compensation Committee of the Board.

In connection with their appointment, each of the New Directors is expected to be granted an inaugural award of 150,000 restricted stock units, deferred stock units, or stock options with an exercise price equal to the closing price of our common stock on the Nasdaq Stock Market on April 2, 2020, and in each case vesting over three years, subject to earlier vesting in the case of a change of control.

Two current members of the Board, James L.L. Tullis and Nicholas Colucci, will be resigning from the Board immediately prior to our 2020 annual meeting of stockholders. In connection with the foregoing, effective April 2, 2020, Michael G. Atieh, a member of the Board, was appointed to the Nominating and Governance Committee of the Board, and Dr. Thomas Errico, a member of the Board, was appointed chairman of the Nominating and Governance Committee of the Board.

The size of the Board will be increased from eight members to 11 members, effective April 2, 2020, and will be reduced to nine members effective immediately prior to our 2020 annual meeting of stockholders.

Migraine

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

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

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

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

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

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

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

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

Market Factors

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

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

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

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

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

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

Cluster Headache

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

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

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

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

The Limitations of Pharmaceutical Treatment Options in Cluster Headache

There is only one FDA-approved commercially available pharmaceutical treatment for the acute treatment of CH, injectable sumatriptan. Patients have typically been limited to fewer than 10 injections per month, primarily due to cost and potential toxicity. In addition, the technical difficulty of subcutaneously self-injecting a medication during a CH attack may also limit use of this therapy. As a result, some patients typically have enough medication to treat, on average, only a fraction of their monthly CH attacks. Prior to gammaCore, there were no approved treatments for the prevention of CH, driving patients to use off-label medications, such as lithium, valproic acid and high-dose verapamil, which have unproven efficacy and the potential for significant toxicity, including adverse cardiac events. In a 2016 market research survey of CH patients, 87% of the respondents were dissatisfied with the then-available treatment options.

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

Cluster Headache Market Factors

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

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

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

Manufacturing

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

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

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

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

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

The generation of our proprietary therapeutic signal does not require custom electronic components. Therefore, we believe long-term manufacturing, supply and quality agreements with electronic component suppliers are not necessary, as all the electronic components used in our products are either high-volume, non-custom commodity components, or are readily available from multiple vendors. The majority of these components have multiple sources, and the few with single sources have been purchased with sufficient reserves to permit continued production while simple product design modifications can be made.

Competition

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

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

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

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

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

Treatments for Cluster Headache

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

Treatments for Migraine

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

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

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

Patents and Patent Applications

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

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

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

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

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

Copyrights, Trademarks and Trade Secrets

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

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

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

Government Regulation

United States

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

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

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

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

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

510(k) Clearance

To obtain 510(k) clearance for a medical device, an applicant must submit to the FDA a premarket notification demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A legally marketed predicate device may include a device that was

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

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

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

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

PMA Approval

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

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

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

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

De Novo Classification

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

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

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

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

Clinical Studies

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

Continuing Regulation

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

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

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

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

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

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

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

International

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

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

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

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

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

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

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

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

Other Regulations

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

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

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

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

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

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

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

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

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

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

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

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

Healthcare Reform

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

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

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

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

Federal Contracting Regulations

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

Employees

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

Company History

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

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and proxy statements, and all amendments thereto, are available free of charge on our Internet website. These reports are posted on our website as soon as reasonably practicable after such reports are electronically filed with the SEC. The public may read and copy any materials that we file with the SEC electronically through the SEC website (www.sec.gov). The information contained on the SEC's website is not incorporated by reference into this prospectus supplement and should not be considered to be part of this prospectus supplement. 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 prospectus supplement is not incorporated by reference herein unless expressly noted.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should consider carefully the risk factors described below and in our in our filings made under the securities laws, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, together with the other information contained in or incorporated by reference in this prospectus supplement and the accompanying prospectus, including our consolidated financial statements and the related notes, before deciding to invest in our common stock. We operate in a changing environment that involves numerous known and unknown risks and uncertainties that could materially adversely affect our operations. If any of such risks occur, our business, financial condition, results of operations and the value of our common stock could be materially and adversely affected. In such case, you may lose all or part of your investment in our common stock.

Risks Related to the Offering

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. If you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $(0.64) per share in the net tangible book value of the common stock. See the section entitled "Dilution" below for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

Our management will have broad discretion over the use of the net proceeds from this offering.

We currently intend to use the net proceeds from this offering for working capital and other general corporate purposes. We have not determined the amounts we plan to spend for various working capital and general corporate purposes or the timing of these expenditures. Accordingly, our management will have considerable discretion in the application of the net proceeds from this offering, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds from this offering are being used appropriately. The net proceeds may be used for corporate purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce income or that lose value.

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 prospectus supplement and others such as:

- announcements related to regulatory clearance to market gammaCore for the treatment of various conditions in the United States;
- results from, or any delays in, clinical trial programs relating to our product candidates;
- announcements of new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- our operating results and financial position;
- changes or developments in laws or regulations applicable to our products;
- any adverse changes in our relationship with any manufacturers or suppliers;
- the success of our efforts to acquire or develop additional products;

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

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

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

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

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

Future issuances of shares of our common stock may cause significant dilution of equity interests of existing holders of common stock and decrease the market price of shares of our common stock.

We have previously issued options, warrants and equity awards that are exercisable into a significant number of shares of our common stock. Should existing holders of options, warrants or equity awards exercise their securities into shares of our common stock, it may cause significant dilution of equity interests of existing holders of our common stock and reduce the market price of shares of our common stock.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Physicians play a significant role in determining the course of a patient's treatment and, as a result, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing our gammaCore therapy to physicians. We have received several 510(k) clearances from the FDA for gammaCore therapy, however, such clearances do not necessitate adoption by physicians. In order for our gammaCore therapy to gain widespread adoption, we must successfully demonstrate to physicians the medical and economic benefits of our gammaCore therapy compared to competitors' products, including (i) BOTOX marketed by Allergan plc, (ii) CGRP receptor agonists marketed by Amgen Inc. (with a co-marketing arrangement with Novartis International AG), Allergan plc, Eli Lilly and Company, and Teva Pharmaceutical Industries Ltd., Biohaven Pharmaceuticals Inc., (iii) lasmiditan, marketed by Eli Lilly, (iv) Vycpti, an intravenous preventive treatment for migraine marketed by H. Lundbeck A/S, and (v) neuromodulation devices that have been marketed for the acute treatment and/or prevention of migraine, including the Cefaly, Eneura, Nerivio, and the sTMS mini devices. We also may face challenges because noninvasive VNS, or nVNS, is relatively new as compared to existing traditional treatments for cluster and migraine headaches. Acceptance of our gammaCore therapy depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost-effectiveness of our gammaCore therapy as compared to our competitors' products and communicating to physicians the proper use of our gammaCore therapy. If we are not successful in convincing physicians of the merits of our gammaCore therapy or educating them on the benefits of our gammaCore therapy, they may not prescribe our gammaCore therapy and we may be unable to increase our sales, sustain our growth or achieve profitability. In addition, we believe support of our products by physicians is essential for market acceptance and adoption. If we do not receive support from physicians or long-term data does not show the benefits of using our gammaCore therapy, physicians may not use it. In such circumstances, our results of operations would be materially adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials;
- the delay or refusal of regulators or institutional review boards, or IRBs, to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;

- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality of the product candidate falling below acceptable standards;
- the inability to manufacture sufficient quantities of our gammaCore therapy to commence or complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

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

We could also encounter delays if a clinical trial is suspended, terminated, or paused by us, as we have done with our Premium II trial, by the IRBs or ethics committees of the institutions at which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In light of the March 2020 FDA clearance, as well as challenges to study protocols, related datasets, and our business arising out of the novel coronavirus pandemic, we may also choose to terminate the Premium II study and take other actions to further reduce operating costs including reductions in our workforce.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risk Related to our Dependence on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

However, we face the risks that:

- We may fail to secure necessary patents, potentially permitting competitors to market competing products and services and make, use or sell products or offer services that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete.
- Patents may not issue from any of our currently pending or future patent applications.
- Our already-granted patents and any future patents may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us, and they may be challenged in a post grant review or inter partes review proceeding, re-examined or invalidated, and/or may be found to be unenforceable or not cover competing processes, products or services.
- Even if our patents are determined by the U.S. Patent and Trademark Office, or USPTO, foreign patent office, or a court to be valid and enforceable, they may not be drafted or interpreted sufficiently broadly to prevent others from marketing products and services similar to ours or designing around our patents. For example, third parties may be able to develop therapies, or make systems or devices, that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or our contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights from third parties to issued patents or pending patent applications covering such technologies to allow us to commercialize our technology. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO to determine priority of invention in the United States. There may be prior public disclosures of which we are not aware that could invalidate our patents or a portion of the claims of our patents. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.
- Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications, our ability to obtain patents, or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Regulation of our Industry

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

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

- the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations (Title 21 CFR);
- CE mark requirements of the European Union, or EU;
- Medical Device Quality Management System Requirements (ISO 13485:2016);
- Occupational Safety and Health Administration requirements; and
- New Jersey Department of Health Services requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment, and exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the Stark Law, in the event that third-party payers require us to be a durable medical equipment, or DME, supplier or we sell our products directly to providers who are DME suppliers that submit claims to such payers. The Stark Law prohibits a physician from making a referral for certain designated health services covered by the Medicare program or Medicaid program, including DME, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, significant civil monetary penalties per claim submitted and exclusion from the federal health care programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA. The statute also provides for significant civil monetary penalties for a circumvention scheme. Various states also have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state;
- The federal civil False Claims Act, which prohibits, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The federal civil False Claims Act can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. Penalties for a federal civil False Claims Act violation include three times the actual damages sustained by the government, plus significant mandatory civil penalties for each false claim, and the potential for exclusion from participation in federal healthcare programs. There are also federal criminal false claims and federal civil monetary penalty laws that carry significant monetary and other penalties for submissions of false or fraudulent claims and statements;

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As a public company, we are required to implement and maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting. Beginning with our second annual report following our IPO, for our fiscal year ended December 31, 2019, management will be required to provide 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.

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

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

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

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

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

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

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

- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

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

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

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

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

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

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

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

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

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

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

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

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

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

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

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

USE OF PROCEEDS

We intend to use the net proceeds from this offering for working capital and general corporate purposes.

As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses of the net proceeds from this offering. Accordingly, we will retain broad discretion over the use of such proceeds.

Pending use of the proceeds as described above or otherwise, we intend to invest the net proceeds in short-term interest-bearing, investment-grade securities.

DIVIDEND POLICY

We have not paid any cash dividends on our common stock to date, and we do not expect to pay cash dividends in the foreseeable future. Future dividend policy will depend on our earnings, capital requirements, financial condition, and other factors considered relevant by our board of directors. There are no non-statutory restrictions on our present ability to pay dividends. Any future determination to pay dividends will be made at the discretion of our board of directors.

DILUTION

The purchaser of Common Stock in this offering will be diluted to the extent of the difference between the price per share of our common stock in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value as of September 30, 2019 was approximately $32.23 million, or approximately $1.10 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of September 30, 2019.

After giving effect to the sale of 5,299,398 shares of common stock in this offering (which excludes any of the Commitment Shares), and after deducting estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2019 would have been approximately $31.9 million, or approximately $1.09 per share of common stock. This represents an immediate decrease in as adjusted net tangible book value of $0.01 per share to our existing stockholders and an immediate dilution of $(0.64) per share to the purchaser in this offering.

Dilution per share to the purchaser in this offering is determined by subtracting net tangible book value per share after this offering from the public offering price per share paid by the purchaser in this offering. The following table illustrates this per share dilution:

Offering price for one share of common stock		$ 0.45
Net tangible book value per share as of September 30, 2019	$ 1.10	
Decrease per share attributable to the purchaser	$ (0.01)	
As adjusted net tangible book value per share after this offering		$ 1.09
Dilution per share to the purchaser		$ (0.64)

The information set forth above is based on 29,468,966 shares of common stock issued and outstanding as of September 30, 2019 and excludes: (i) 2,355,366 shares of our common stock reserved for issuance upon the exercise of outstanding options at a weighted average exercise price of $11.18 per share; (ii) 715,199 shares of our common stock reserved for issuance upon the exercise of outstanding warrants at a weighted average exercise price of $12.29 per share; and (iii) 1,246,315 shares of our common stock reserved for issuance upon settlement of restricted stock units.

The above illustration of dilution per share to the purchaser in this offering assumes no exercise of outstanding options, warrants or equity awards into common stock. The exercise of outstanding options, warrants or equity awards having an exercise price less than the offering price will increase dilution to the purchaser in this offering. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

EXPERTS

The consolidated financial statements of electroCore, Inc., subsidiaries and affiliate as of December 31, 2018 and 2017, and for each of the years in the two-year period ended December 31, 2018, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

PLAN OF DISTRIBUTION

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering up to $25,000,000 in shares of our common stock, as well as up to 692,514 shares of common stock as commitment shares, that have been or may be issued by us directly to Lincoln Park under the Purchase Agreement. This prospectus supplement and the accompanying prospectus also cover the resale of these shares by Lincoln Park to the public.

Upon the terms and subject to the conditions set forth in the Purchase Agreement, we may direct Lincoln Park to purchase an aggregate of up to $25,000,000 of shares of our common stock over the 36-month term of the Purchase Agreement. The Purchase Agreement provides that, from time-to-time over the term of the Purchase Agreement, on any trading day at our sole discretion, we may require Lincoln Park to purchase up to 200,000 shares of our common stock subject to certain increases in accordance with the terms of the Purchase Agreement. In addition, upon notice to Lincoln Park, we may, from time to time and at our sole discretion subject to the terms of the Purchase Agreement, direct Lincoln Park to purchase additional shares of our common stock in “accelerated purchases,” “additional accelerated purchases” and “tranche purchases” each as set forth in the Purchase Agreement. The purchase price per share is based on the market price of our common stock at the time of sale as computed under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement. See the section entitled “Lincoln Park Transaction” above.

Lincoln Park is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that it will use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made on the Nasdaq Global Select Market at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions. We know of no existing arrangements between Lincoln Park and any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus supplement. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay the expenses incident to the registration under the Securities Act of the offer and sale of the shares covered by this prospectus supplement to Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus supplement or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park represented to us that at no time prior to the date of the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered by this prospectus supplement.

This offering will terminate on the date that all shares offered by this prospectus supplement have been sold to Lincoln Park or on any earlier date we provide notice of termination to Lincoln Park.

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.. Our common stock is listed on the Nasdaq Global Select Market under the symbol “ECOR.”

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon by Dentons US LLP, New York, New York. As of the date of this prospectus supplement, members of Dentons US LLP own shares of our common stock with a market value in excess of $50,000.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and periodic reports, proxy statements and other information with the SEC. Our SEC filings are available to the public from the SEC’s website at www.sec.gov. We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please contact the Corporate Secretary at the following address or telephone number: electroCore, Inc., 150 Allen Road, Suite 201, Basking Ridge, New Jersey 07920, Attention: Corporate Secretary; (973) 290-0097. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus supplement.

We maintain our website at www.electrocore.com. Our website and the information contained therein or connected thereto are not incorporated into this prospectus supplement.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act relating to the securities we are offering by this prospectus supplement. This prospectus supplement does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us and our securities. Statements contained in this prospectus supplement and accompanying prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the registration statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described above.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents filed with the SEC listed below:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 28, 2019.
- Our Quarterly Reports on Form 10-Q filed with the SEC on May 15, 2019, August 14, 2019, and November 14, 2019.
- Our Current Reports on Form 8-K and amendment to Current Report on Form 8-K, filed with the SEC on May 30, 2019, June 4, 2019, June 7, 2019, June 10, 2019, July 15, 2019; September 25, 2019, October 2, 2019, December 27, 2019, March 26, 2020 and March 27, 2020.
- The description of our capital stock included under the caption "Description of Capital Stock" of the prospectus included in the Registration Statement on Form S-1 (File No. 333-225084) filed with the SEC on June 11, 2018.

In addition, all documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act on or after the date of this prospectus supplement and accompanying prospectus and prior to the termination of the offering of the securities to which this prospectus supplement and accompanying prospectus relates, shall be deemed to be incorporated by reference in this prospectus supplement and accompanying prospectus and to be a part hereof from the date of filing of such documents. However, any documents or portions thereof, whether specifically listed above or filed in the future, that are not deemed "filed" with the SEC, including without limitation any information furnished pursuant to Item 2.02 or 7.01 of Form 8-K or certain exhibits furnished pursuant to Item 9.01 of Form 8-K, shall not be deemed to be incorporated by reference in this prospectus supplement and accompanying prospectus

Any statement in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for the purposes of this prospectus supplement to the extent that a statement contained herein or in any other subsequently filed document which also is incorporated or deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

$50,000,000

electroCore, Inc.

Debt Securities
Preferred Stock
Common Stock
Warrants
Rights
Units

From time to time, we may offer and sell up to an aggregate of $50,000,000 of any combination of the securities described in this prospectus, either individually or in combination. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

When we decide to sell particular securities, we will provide you with the specific terms and the offering price of the securities we are then offering in one or more prospectus supplements to this prospectus. The prospectus supplement may add to, change or update information contained in this prospectus. The prospectus supplement may also contain important information about U.S. federal income tax consequences. You should carefully read this prospectus, together with any prospectus supplements and information incorporated by reference in this prospectus and any prospectus supplements, before you decide to invest. **This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.**

Our common stock is quoted on The NASDAQ Global Select Market under the trading symbol “ECOR.” Any common stock sold pursuant to this prospectus or any prospectus supplement will be listed on that exchange, subject to official notice of issuance. Each prospectus supplement to this prospectus will contain information, where applicable, as to any other listing on any national securities exchange of the securities covered by the prospectus supplement.

We may offer and sell the securities described in this prospectus to or through one or more underwriters, dealers or agents, or directly to purchasers on an immediate, continuous or delayed basis. The names of any underwriters, dealers or agents involved in the sale of any securities, the specific manner in which they may be offered and any applicable commissions or discounts will be set forth in an accompanying prospectus supplement covering the sales of those securities.

Investing in our securities involves significant risks. See “Risk Factors” beginning on page 4.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is September 5, 2019.

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This prospectus is part of a registration statement the Company filed with the Securities and Exchange Commission. You should rely only on the information the Company has provided or incorporated by reference in this prospectus or any prospectus supplement. The Company has not authorized anyone to provide you with additional or different information. The Company is not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the prospectus.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the U.S. Securities and Exchange Commission (the "SEC") utilizing a "shelf" registration process or continuous offering process, which allows the Company to offer and sell any combination of the securities described in this prospectus in one or more offerings. Using this prospectus, we may offer up to a total dollar amount of $50,000,000 of these securities.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities pursuant to this registration statement and the prospectus contained herein, we will provide a prospectus supplement that will contain specific information about the terms of that offering. That prospectus supplement may include additional risk factors about us and the terms of that particular offering. Prospectus supplements may also add to, update or change the information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in such prospectus supplement. In addition, as described in the section entitled "Where You Can Find More Information," we have filed and plan to continue to file other documents with the SEC that contain information about our business. Before you decide whether to invest in any of these securities, you should read this prospectus, the prospectus supplement that further describes the offering of these securities and the information we file with the SEC.

In this prospectus and any prospectus supplement, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and certain information incorporated herein by reference contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this prospectus that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements.

Factors that could cause or contribute to such differences include, but are not limited to, (i) those included in our Annual Report on Form 10-K dated December 31, 2018, (ii) those contained in other SEC reports described under "Risk Factors," (iii) those described elsewhere in this prospectus, and (iv) other factors that we may publicly disclose from time to time. Furthermore, such forward-looking statements speak only as of the date made. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

ABOUT THE COMPANY

Business Overview

We are a commercial stage bioelectronic medicine company with a proprietary non-invasive vagus nerve stimulation, or nVNS, therapy. nVNS is a platform therapy that modulates neurotransmitters and immune function through its effects on both the peripheral and central nervous systems. We are initially focused on neurology and our therapy, gammaCore, is cleared by the U.S. Food and Drug Administration, or FDA, for use by adults for the following three neurology indications: the acute treatment of pain associated with each of migraine and episodic cluster headache; and the prevention of cluster headaches. In neurology, we intend to pursue further label expansions to include prevention of migraine. Our ATOM trial to pursue label expansion into migraine in adolescents is currently on hold pending further developments in the Company's business plan. Finally, we are considering the potential for new indications in several additional indications as our nVNS technology is being broadly studied in a number of investigator-initiated studies.

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

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

VNS works through suppressing neural circuits involved in pain sensation and neuroexcitatory activity in the brain, modulating the release of a variety of neurotransmitters, inducing changes in the autonomic signaling and inducing anti-inflammatory effects.

In January 2018, the FDA cleared our gammaCore therapy for the acute treatment of pain associated with migraine in adults. Migraine is a debilitating primary headache condition that affects approximately 12% of the adult population. Some reports suggest that up to 60% of migraine suffers are dissatisfied with, or have contraindications to, the current standard of care treatments for migraine, such as "triptan" medications. In April 2017, the FDA cleared gammaCore for the acute treatment of pain associated with episodic cluster headache ("CH") and in December 2018, the FDA cleared gammaCore for the prevention of CH. CH is an extremely painful form of headache affecting approximately 350,000 people in the United States. Prior to gammaCore, injectable sumatriptan was the only FDA-approved, commercially available acute CH treatment, and there was no FDA approved therapy for the prevention of CH; gammaCore remains the only FDA-cleared treatment available as both an acute and preventative therapy for CH. According to a 2016 market research survey, 87% of respondents reported dissatisfaction with the then-available treatment options for managing CH.

The first three clearances of our gammaCore therapy were facilitated by the FDA's creation of a new regulatory category: External Vagus Nerve Stimulator for Headache (21 CFR 882-5892). Based on this category's description, we anticipate that some additional label expansions may be possible through the pathway under Section 510(k) of the Federal Drug and Cosmetic Act. In July 2019, the FDA accepted for review our 510(k) premarket notification for a new indication for use of gammaCore for the prevention of migraine. We expect to

receive the FDA's decision by the end of 2019. Because the new indication of migraine prevention is supported largely by the Premium 1 study, which showed a trend in favor of gammaCore over a sham device in reducing the number of migraines per month but failed to achieve statistical significance, the FDA may not clear gammaCore for this use based on the Premium 1 results. Accordingly, we continue to enroll subjects in the Premium 2 clinical trial to support the label expansion for migraine prevention, if necessary, and to support the commercialization of gammaCore as a migraine prevention therapy should this indication receive FDA clearance. We expect to complete enrollment in Premium 2 during the first half of 2020.

Our Therapy Delivery Platform

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

Our therapy is prescription-only, and patients self-administer discrete doses using a handheld unit. gammaCore Sapphire is a non-disposable, rechargeable and reloadable option for patients, with the therapy being dispensed through a prescription from a specialty pharmacy. After the initial prescription is filled, access to therapy is refilled monthly through the input of a unique, prescription-only authorization code. This code is currently delivered in the form of an RFID card, dispensed by mail by our specialty pharmacy distribution partner. In the future this refill may be dispensed directly through the internet using Bluetooth technology.

The prior iteration of the gammaCore delivery device was not reloadable and rechargeable and was supplanted by the gammaCore Sapphire during the third quarter of 2018. While we do not intend to market the non-reloadable, disposable version of our gammaCore product in markets where the gammaCore Sapphire is launched, in select cases, we may continue to use the prior gammaCore product, such as in clinical studies where a rechargeable version is not necessary. Certain customers, such as the Veterans Administration and the Department of Defense, may also continue to use the prior iteration of the gammaCore delivery device.

Trademark Notice

RISK FACTORS

Before you invest in any of the Company's securities, in addition to the other information in this prospectus and the applicable prospectus supplement, you should carefully consider (i) the risk factors contained in the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, which are incorporated by reference into this prospectus, (ii) all of the other information included or incorporated by reference in this prospectus, and (iii) the applicable prospectus supplement, as the same may be updated from time to time by the Company's future filings under the Exchange Act.

The risks and uncertainties described herein are not the only ones facing the Company. Additional risks and uncertainties not presently known to the Company or that the Company currently deems immaterial may also impair its business or operations. Any adverse effect on the Company's business, financial condition or operating results could result in a decline in the value of the securities and the loss of all or part of your investment. The prospectus supplement applicable to each series of securities the Company offers may contain a discussion of additional risks applicable to an investment in the Company and the securities the Company is offering under that prospectus supplement.

USE OF PROCEEDS

Unless otherwise indicated in the prospectus supplement, the Company will use the net proceeds from the sale of securities offered by this prospectus for working capital and general corporate purposes. As of the date of this prospectus supplement, the Company has not identified any specific and material proposed uses of the anticipated proceeds.

Our expected use of net proceeds from the sale of securities offered by this prospectus represents our current intentions based upon our plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of any offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including the factors described under the heading "Risk Factors" in this prospectus. As a result, management will have broad discretion in its application of the net proceeds, and investors will be relying on our judgment in such application.

Pending use of net proceeds from the sale of securities offered by this prospectus, we may invest in short- and intermediate-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

RATIO OF EARNINGS TO FIXED CHARGES

If the Company offers debt securities and/or preference equity securities under this prospectus, then the Company will, if required at that time, provide a ratio of earnings to fixed charges and/or ratio of combined fixed charges and preference dividends to earnings, respectively, in the applicable prospectus supplement for such offering.

PLAN OF DISTRIBUTION

The Company may sell the securities being offered by it in this prospectus pursuant to underwritten public offerings, negotiated transactions, block trades or any combination of such methods. The Company may sell the securities to or through underwriters, dealers, agents or directly to one or more purchasers. The Company and its agents reserve the right to accept and to reject, in whole or in part, any proposed purchase of securities. A prospectus supplement or post-effective amendment, which the Company will file each time the Company effects an offering of any securities, will provide the names of any underwriters, dealers or agents, if any, involved in the sale of such securities, and any applicable fees, commissions, or discounts to which such persons shall be entitled to in connection with such offering.

The Company and its agents, dealers and underwriters, as applicable, may sell the securities being offered by the Company in this prospectus from time to time in one or more transactions at:

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale;
- prices related to such prevailing market prices;
- varying prices determined at the time of sale; or
- negotiated prices.

The Company may determine the price or other terms of the securities offered under this prospectus by use of an electronic auction. The Company will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the underwriters' obligations in the applicable prospectus supplement or amendment.

The Company may solicit directly offers to purchase securities. The Company may also designate agents from time to time to solicit offers to purchase securities. Any agent that the Company designates, who may be deemed to be an underwriter as such term is defined in the Securities Act, may then resell such securities to the public at varying prices to be determined by such agent at the time of resale.

The Company may engage in at the market offerings of the Company's common stock. An at the market offering is an offering of the Company's common stock at other than a fixed price, and is conducted to or through a market maker. The Company shall name any underwriter that the Company engages for an at the market offering in a post-effective amendment to the registration statement containing this prospectus. In the related prospectus supplement, the Company shall also describe any additional details of the Company's arrangement with such underwriter, including commissions or fees paid or discounts offered by the Company, and whether such underwriter is acting as principal or agent.

If the Company uses underwriters to sell securities, the Company will enter into an underwriting agreement with the underwriters at the time of the sale to them, which agreement shall be filed as an exhibit to the related prospectus supplement. Underwriters may also receive commissions from purchasers of the securities. Underwriters may also use dealers to sell securities. In such an event, the dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents.

Under agreements that they may enter into with the Company, underwriters, dealers, agents and other persons may be entitled to (i) indemnification by the Company against certain civil liabilities, including liabilities under the Securities Act or (ii) contribution with respect to payments which they may be required to make in respect of such liabilities. Underwriters and agents may engage in transactions with, or perform services for, the Company in the ordinary course of business.

If so indicated in the applicable prospectus supplement, the Company may authorize underwriters, dealers or other persons to solicit offers by certain institutions to purchase the securities offered by the Company under this prospectus pursuant to contracts providing for payment and delivery on a future date or dates. The obligations of any purchaser under these contracts will be subject only to those conditions described in the applicable prospectus supplement, and the prospectus supplement will set forth the price to be paid for securities pursuant to those contracts and the commissions payable for solicitation of the contracts.

Any underwriter may engage in over-allotment, stabilizing and syndicate short covering transactions and penalty bids in accordance with Regulation M of the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions involve bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate short covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the underwriters to reclaim selling concessions from dealers when the securities originally sold by such dealers are purchased in covering transactions to cover syndicate short positions. These transactions may cause the price of the securities sold in an offering to be higher than it would otherwise be. These transactions, if commenced, may be discontinued by the underwriters at any time.

The Company's common stock is quoted on The NASDAQ Global Select Market under the trading symbol "ECOR." The other securities are not listed on any securities exchange or other stock market and, unless the Company states otherwise in the applicable prospectus supplement, the Company does not intend to apply for listing of the other securities on any securities exchange or other stock market. Any underwriters to whom the Company sells securities for public offering and sale may make a market in the securities that they purchase, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. Accordingly, the Company gives you no assurance as to the development or liquidity of any trading market for the securities.

The anticipated date of delivery of the securities offered hereby will be set forth in the applicable prospectus supplement relating to each offering.

In order to comply with certain state securities laws, if applicable, the securities may be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the securities may not be sold unless the securities have been registered or qualified for sale in such state or an exemption from regulation or qualification is available and is complied with. Sales of securities must also be made by the Company in compliance with all other applicable state securities laws and regulations.

The Company shall pay all expenses of the registration of the securities.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information the Company includes in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that the Company may offer under this prospectus. While the terms the Company has summarized below will apply generally to any future debt securities the Company may offer under this prospectus, the Company will describe the particular terms of any debt securities that the Company may offer in more detail in the applicable prospectus supplement. The terms of any debt securities the Company offers under a prospectus supplement may differ from the terms described below. However, no prospectus supplement shall fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. As of June 30, 2019, the Company had no outstanding indebtedness.

The Company will issue the senior debt securities under the senior indenture that the Company will enter into with the trustee named in the senior indenture. The Company will issue the subordinated debt securities under the subordinated indenture that the Company will enter into with the trustee named in the subordinated indenture. The Company has filed forms of these documents as exhibits to the registration statement which includes this prospectus. The Company uses the term “indentures” in this prospectus to refer to both the senior indenture and the subordinated indenture.

The indentures will be qualified under the Trust Indenture Act of 1939, as amended (the “Trust Indenture Act”). The Company uses the term “trustee” to refer to either the senior trustee or the subordinated trustee, as applicable.

The following summaries of material provisions of the senior debt securities, the subordinated debt securities and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities. Except as the Company may otherwise indicate, the terms of the senior indenture and the subordinated indenture are identical.

General

Debt securities may be issued in separate series without limitation as to aggregate principal amount. The Company may specify a maximum aggregate principal amount for the debt securities of any series.

The Company is not limited as to the amount of debt securities it may issue under the indentures. The prospectus supplement will set forth:

- whether the debt securities will be senior or subordinated;
- the offering price;
- the title;
- any limit on the aggregate principal amount;
- the person who shall be entitled to receive interest, if other than the record holder on the record date;
- the date the principal will be payable;
- the interest rate, if any, the date interest will accrue, the interest payment dates and the regular record dates;
- the place where payments may be made;
- any mandatory or optional redemption provisions;
- if applicable, the method for determining how the principal, premium, if any, or interest will be calculated by reference to an index or formula;

- if other than U.S. currency, the currency or currency units in which principal, premium, if any, or interest will be payable and whether the Company or the holder may elect payment to be made in a different currency;
- the portion of the principal amount that will be payable upon acceleration of stated maturity, if other than the entire principal amount;
- if the principal amount payable at stated maturity will not be determinable as of any date prior to stated maturity, the amount which will be deemed to be the principal amount;
- any defeasance provisions if different from those described below under “Satisfaction and Discharge; Defeasance;”
- any conversion or exchange provisions;
- any obligation to redeem or purchase the debt securities pursuant to a sinking fund;
- whether the debt securities will be issuable in the form of a global security;
- any subordination provisions, if different from those described below under “Subordinated Debt Securities;”
- any deletions of, or changes or additions to, the events of default or covenants; and
- any other specific terms of such debt securities.

Unless otherwise specified in the prospectus supplement:

- the debt securities will be registered debt securities; and
- registered debt securities denominated in U.S. dollars will be issued in denominations of $1,000 or an integral multiple of $1,000.

Debt securities may be sold at a substantial discount below their stated principal amount, bearing no interest or interest at a rate which at the time of issuance is below market rates.

Exchange and Transfer

Debt securities may be transferred or exchanged at the office of the security registrar or at the office of any transfer agent designated by the Company.

The Company will not impose a service charge for any transfer or exchange, but the Company may require holders to pay any tax or other governmental charges associated with any transfer or exchange.

In the event of any potential redemption of debt securities of any series, the Company will not be required to:

- issue, register the transfer of, or exchange, any debt security of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt security of that series selected for redemption, in whole or in part, except the unredeemed portion being redeemed in part.

The Company may initially appoint the trustee as the security registrar. Any transfer agent, in addition to the security registrar, initially designated by the Company will be named in the prospectus supplement. The Company may designate additional transfer agents or change transfer agents or change the office of the transfer agent. However, the Company will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

Global Securities

The debt securities of any series may be represented, in whole or in part, by one or more global securities. Each global security will:

- be registered in the name of a depositary that the Company will identify in a prospectus supplement;
- be deposited with the depositary or nominee or custodian; and
- bear any required legends.

No global security may be exchanged in whole or in part for debt securities registered in the name of any person other than the depositary or any nominee unless:

- the depositary has notified the Company that it is unwilling or unable to continue as depositary or has ceased to be qualified to act as depositary;
- an event of default is continuing; or
- any other circumstances described in a prospectus supplement.

As long as the depositary, or its nominee, is the registered owner of a global security, the depositary or nominee will be considered the sole owner and holder of the debt securities represented by the global security for all purposes under the indenture. Except in the above limited circumstances, owners of beneficial interests in a global security:

- will not be entitled to have the debt securities registered in their names,
- will not be entitled to physical delivery of certificated debt securities, and
- will not be considered to be holders of those debt securities under the indentures.

Payments on a global security will be made to the depositary or its nominee as the holder of the global security. Some jurisdictions have laws that require that certain purchasers of securities take physical delivery of such securities in definitive form. These laws may impair the ability to transfer beneficial interests in a global security.

Institutions that have accounts with the depositary or its nominee are referred to as “participants.” Ownership of beneficial interests in a global security will be limited to participants and to persons that may hold beneficial interests through participants. The depositary will credit, on its book-entry registration and transfer system, the respective principal amounts of debt securities represented by the global security to the accounts of its participants.

Ownership of beneficial interests in a global security will be shown on and effected through records maintained by the depositary, with respect to participants’ interests, or any participant, with respect to interests of persons held by participants on their behalf.

Payments, transfers and exchanges relating to beneficial interests in a global security will be subject to policies and procedures of the depositary.

The depositary policies and procedures may change from time to time. Neither the Company nor the trustee will have any responsibility or liability for the depositary’s or any participant’s records with respect to beneficial interests in a global security.

Payment and Paying Agent

The provisions of this paragraph will apply to debt securities unless otherwise indicated in the prospectus supplement. Payment of interest on a debt security on any interest payment date will be made to the person in

whose name the debt security is registered at the close of business on the regular record date. Payment on debt securities of a particular series will be payable at the office of a paying agent or paying agents designated by the Company. However, at the Company's option, the Company may pay interest by mailing a check to the record holder. The corporate trust office initially will be designated as the Company's sole paying agent.

The Company may also name any other paying agents in the prospectus supplement. The Company may designate additional paying agents, change paying agents or change the office of any paying agent. However, the Company will be required to maintain a paying agent in each place of payment for the debt securities of a particular series.

All moneys paid by the Company to a paying agent for payment on any debt security which remain unclaimed at the end of two years after such payment was due will be repaid to the Company. Thereafter, the holder may look only to the Company for such payment.

Consolidation, Merger and Sale of Assets

The Company may not consolidate with or merge into any other person, in a transaction in which it is not the surviving corporation, or convey, transfer or lease the Company's properties and assets substantially as an entirety to, any person, unless:

- the Company shall be the surviving or continuing corporation in the transaction;
- the successor assumes the Company's obligations on the debt securities and under the indenture;
- immediately after giving effect to the transaction, no default or event of default shall have happened and be continuing; and
- certain other conditions are met.

If the debt securities are convertible for the Company's other securities or securities of other entities, the person with whom the Company consolidates or merges or to whom the Company sells all of its property must make provisions for the conversion of the debt securities into securities which the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

Events of Default

Unless the Company informs you otherwise in the prospectus supplement, the indenture will define an event of default with respect to any series of debt securities as one or more of the following events:

(1) failure to pay principal of or any premium on any debt security of that series when due and payable;

(2) failure to pay any interest on any debt security of that series when it becomes due and payable, and continuation of that failure for a period of 90 days (unless the entire amount of such payment is deposited by the Company with the trustee or paying agent prior to the expiration of the 90-day period);

(3) failure to deposit any sinking fund payment, when and as due in respect of any debt security of that series;

(4) failure to perform or breach of any other covenant or warranty by the Company in the indenture (other than a covenant or warranty that has been included in the indenture solely for the benefit of a series of debt securities other than the series), which failure continues uncured for a period of 90 days after the Company receives the notice required in the indenture;

(5) the Company's bankruptcy, insolvency or reorganization; and

(6) any other event of default with respect to debt securities of that series that is described in the applicable prospectus supplement accompanying this prospectus.

An event of default of one series of debt securities is not necessarily an event of default for any other series of debt securities.

If an event of default, other than an event of default described in clause (5) above, shall occur and be continuing, after applicable notice and cure periods set forth in the indenture, either the trustee or the holders of at least 25% in aggregate principal amount of the outstanding securities of that series may declare the principal amount of the debt securities of that series to be due and payable immediately.

If an event of default described in clause (5) above shall occur, the principal amount of all the debt securities of that series will automatically become immediately due and payable. Any payment by the Company on the subordinated debt securities following any such acceleration will be subject to the subordination provisions described below under “Subordinated Debt Securities.”

After acceleration the holders of a majority in aggregate principal amount of the outstanding securities of that series may, under certain circumstances, rescind and annul such acceleration if all events of default, other than the non-payment of accelerated principal, or other specified amount, have been cured or waived.

Other than the duty to act with the required care during an event of default, the trustee will not be obligated to exercise any of its rights or powers at the request of the holders unless the holders shall have offered to the trustee security and indemnity satisfactory to it against the costs, expenses and liabilities to be incurred in compliance with such request.

Generally, the holders of a majority in aggregate principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee.

A holder will not have any right to institute any proceeding under the indentures, or for the appointment of a receiver or a trustee, or for any other remedy under the indentures, unless:

(1) the holder has previously given to the trustee written notice of a continuing event of default with respect to the debt securities of that series;

(2) the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made a written request and have offered reasonable indemnity to the trustee to institute the proceeding; and

(3) the trustee has failed to institute the proceeding and has not received direction inconsistent with the original request from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series within 90 days after the original request.

A holder may not use the indenture to prejudice the rights of any holder, or to obtain or to seek to obtain priority or preference over another holder or to enforce any right under the indenture, except in the manner provided in the indenture and for the equal and ratable benefit of all holders (it being understood that the trustee does not have an affirmative duty to ascertain whether or not such actions or forbearances are unduly prejudicial to such holders).

Holders may, however, sue to enforce the payment of principal, premium or interest on any debt security on or after the due date or to enforce the right, if any, to convert any debt security without following the procedures listed in (1) through (3) above.

The Company will furnish the trustee an annual statement by its officers as to whether or not the Company is in default in the performance of the indenture and, if so, specifying all known defaults.

Modification and Waiver

The Company and the trustee may make modifications and amendments to the indentures with the consent of the holders of a majority in aggregate principal amount of the outstanding securities of each series affected by the modification or amendment.

However, neither the Company nor the trustee may make any modification or amendment without the consent of the holder of each outstanding security of that series affected by the modification or amendment if such modification or amendment would:

- change the stated maturity of any debt security;
- reduce the principal, premium, if any, or interest on any debt security;
- reduce the principal of an original issue discount security or any other debt security payable on acceleration of maturity;
- reduce the rate of interest on any debt security;
- change the currency in which any debt security is payable;
- impair the right to enforce any payment after the stated maturity or redemption date;
- waive any default or event of default in payment of the principal of, premium or interest on any debt security;
- waive a redemption payment or modify any of the redemption provisions of any debt security;
- adversely affect the right to convert any debt security in any material respect; or
- change the provisions in the indenture that relate to modifying or amending the indenture.

After any amendment becomes effective, the Company will mail to the holders a notice briefly describing such amendment.

Satisfaction and Discharge; Defeasance

The Company may be discharged from its obligations on the debt securities of any series that have matured or will mature or be redeemed within one year if the Company deposits with the trustee enough cash to pay all the principal, interest and any premium due to the stated maturity date or redemption date of the debt securities.

Each indenture will contain a provision that permits the Company to elect:

- to be discharged from all of the Company’s obligations, subject to limited exceptions, with respect to any series of debt securities then outstanding; and/or
- to be released from the Company’s obligations under the following covenants and from the consequences of an event of default resulting from a breach of these covenants: (1) the subordination provisions under a subordinated indenture; and (2) covenants as to payment of taxes and maintenance of corporate existence.

To make either of the above elections, the Company must deposit in trust with the trustee enough money to pay in full the principal, interest and premium on the debt securities. This amount may be made in cash and/or U.S. or foreign government obligations. As a condition to either of the above elections, the Company must deliver to the trustee an opinion of counsel that the holders of the debt securities will not recognize income, gain or loss for Federal income tax purposes as a result of the action.

If any of the above events occurs, the holders of the debt securities of the series will not be entitled to the benefits of the indenture, except for the rights of holders to receive payments on debt securities or the registration of transfer and exchange of debt securities and replacement of lost, stolen or mutilated debt securities.

Notices

Notices to holders will be given by mail to the addresses of the holders in the security register.

Governing Law; Waiver of Jury Trial

The indentures and the debt securities will be governed by, and construed in accordance with, the laws of the State of New York.

The indentures provide that we, the trustee and the holders of the debt securities irrevocably waive the right to trial by jury to the extent permitted by applicable law in respect of any legal proceeding, which could include those relating to claims under the federal securities laws, in connection with the indentures, the debt securities and the transactions contemplated thereby. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the indentures or the debt securities with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the indentures and the debt securities, by a court of the State of New York or a federal court applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will, among other things, consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this would be the case with respect to the indentures and the debt securities, however, there may be other bases upon which New York courts will not enforce a jury trial waiver provision. No condition, stipulation or provision of the indentures or the debt securities serves, or can serve, as a waiver by any holder or by us or the trustee of compliance with any provision of the federal securities laws or the rules and regulations thereunder.

Regarding the Trustee

The indentures will limit the right of the trustee, should it become a creditor of the Company, to obtain payment of claims or secure its claims.

The trustee will be permitted to engage in certain other transactions. However, if the trustee, acquires any conflicting interest within the meaning of the Trust Indenture Act, and there is a default under the indenture with respect to debt securities of any series for which they are the trustee, the trustee must eliminate the conflict or resign.

Subordinated Debt Securities

Payment on subordinated debt securities will, to the extent provided in the indenture, be subordinated in right of payment to the prior payment in full of all of the Company’s senior indebtedness. Subordinated debt securities also are effectively subordinated to all debt and other liabilities, including trade payables and lease obligations, if any, of the Company’s subsidiaries.

Upon any distribution of the Company’s assets upon any dissolution, winding up, liquidation or reorganization, the payment of the principal of and interest on subordinated debt securities will be subordinated in right of payment to the prior payment in full in cash or other payment satisfactory to the holders of senior indebtedness of all senior indebtedness. In the event of any acceleration of the subordinated debt securities because of an event of default, the holders of any senior indebtedness would be entitled to payment in full in cash or other payment satisfactory to such holders of all senior indebtedness obligations before the holders of subordinated debt securities are entitled to receive any payment or distribution. The indentures will require the Company to promptly notify holders of designated senior indebtedness if payment of subordinated debt securities is accelerated because of an event of default.

The Company may not make any payment on subordinated debt securities, including upon redemption at the option of the holder of any subordinated debt securities or at the Company's option, if:

- a default in the payment of the principal, premium, if any, interest, rent or other obligations in respect of designated senior indebtedness occurs and is continuing beyond any applicable period of grace, which is called a "payment default"; or

- a default other than a payment default on any designated senior indebtedness occurs and is continuing that permits holders of designated senior indebtedness to accelerate its maturity, and the trustee receives notice of such default, which is called a "payment blockage notice" from the Company or any other person permitted to give such notice under the indenture, which is called a "non-payment default".

The Company may resume payments and distributions on subordinated debt securities:

- in the case of a payment default, upon the date on which such default is cured or waived or ceases to exist; and

- in the case of a non-payment default, the earlier of the date on which such nonpayment default is cured or waived or ceases to exist and 179 days after the date on which the payment blockage notice is received by the trustee, if the maturity of the designated senior indebtedness has not been accelerated.

No new period of payment blockage may be commenced pursuant to a payment blockage notice unless 365 days have elapsed since the initial effectiveness of the immediately prior payment blockage notice and all scheduled payments of principal, premium and interest, including any liquidated damages, on the notes that have come due have been paid in full in cash. No non-payment default that existed or was continuing on the date of delivery of any payment blockage notice shall be the basis for any later payment blockage notice unless the non-payment default is based upon facts or events arising after the date of delivery of such payment blockage notice.

If the trustee or any holder of the notes receives any payment or distribution of the Company's assets in contravention of the subordination provisions on subordinated debt securities before all senior indebtedness is paid in full in cash, property or securities, including by way of set-off, or other payment satisfactory to holders of senior indebtedness, then such payment or distribution will be held in trust for the benefit of holders of senior indebtedness or their representatives to the extent necessary to make payment in full in cash or payment satisfactory to the holders of senior indebtedness of all unpaid senior indebtedness.

In the event of the Company's bankruptcy, dissolution or reorganization, holders of senior indebtedness may receive more, ratably, and holders of subordinated debt securities may receive less, ratably, than the Company's other creditors (including the Company's trade creditors). This subordination will not prevent the occurrence of any event of default under the indenture.

Unless the Company informs you otherwise in the prospectus supplement, the Company will not be prohibited from incurring debt, including senior indebtedness, under any indenture relating to subordinated debt securities. The Company may from time to time incur additional debt, including senior indebtedness.

The Company is obligated to pay reasonable compensation to the trustee and to indemnify the trustee and certain agents against certain losses, liabilities or expenses incurred by the trustee in connection with its duties relating to subordinated debt securities. The trustee's claims for these payments will generally be senior to those of noteholders in respect of all funds collected or held by the trustee.

Certain Definitions

"indebtedness" means:

(1) all indebtedness, obligations and other liabilities for borrowed money, including overdrafts, foreign exchange contracts, currency exchange agreements, interest rate protection agreements, and any loans

or advances from banks, or evidenced by bonds, debentures, notes or similar instruments, other than any account payable or other accrued current liability or obligation incurred in the ordinary course of business in connection with the obtaining of materials or services;

(2) all reimbursement obligations and other liabilities with respect to letters of credit, bank guarantees or bankers' acceptances;

(3) all obligations and liabilities in respect of leases required in conformity with generally accepted accounting principles to be accounted for on the Company's balance sheet;

(4) all obligations and liabilities, contingent or otherwise, as lessee under leases for facility equipment (and related assets leased together with such equipment) and under any lease or related document (including a purchase agreement, conditional sale or other title retention or synthetic lease agreement) in connection with the lease of real property or improvement thereon (or any personal property included as part of any such lease) which provides that such Person is contractually obligated to purchase or cause a third party to purchase the leased property or pay an agreed upon residual value of the leased property, including the obligations under such lease or related document to purchase or cause a third party to purchase such leased property (whether or not such lease transaction is characterized as an operating lease or a capitalized lease in accordance with GAAP) or pay an agreed upon residual value of the leased property to the lessor;

(5) all obligations with respect to an interest rate or other swap, cap or collar agreement or other similar instrument or agreement or foreign currency hedge, exchange, purchase agreement or other similar instrument or agreement;

(6) all direct or indirect guaranties or similar agreements in respect of, and the Company's obligations or liabilities to purchase, acquire or otherwise assure a creditor against loss in respect of, indebtedness, obligations or liabilities of others of the type described in (1) through (5) above;

(7) any indebtedness or other obligations described in (1) through (6) above secured by any mortgage, pledge, lien or other encumbrance existing on property which is owned or held by the Company; and

(8) any and all refinancings, replacements, deferrals, renewals, extensions and refundings of, or amendments, modifications or supplements to, any indebtedness, obligation or liability of the kind described in clauses (1) through (7) above.

"senior indebtedness" means the principal, premium, if any, interest, including any interest accruing after bankruptcy, and rent or termination payment on or other amounts due on the Company's current or future indebtedness, whether created, incurred, assumed, guaranteed or in effect guaranteed by the Company, including any deferrals, renewals, extensions, refundings, amendments, modifications or supplements to the above. However, senior indebtedness does not include:

- indebtedness that expressly provides that it shall not be senior in right of payment to subordinated debt securities or expressly provides that it is on the same basis or junior to subordinated debt securities;
- the Company's indebtedness to any of the Company's majority-owned subsidiaries; and
- subordinated debt securities.

DESCRIPTION OF PREFERRED STOCK

As of the date of this prospectus, the Company has authorized 10,000,000 shares of preferred stock, par value $.001 per share, none of which are outstanding. Under the Company's Certificate of Incorporation, the Company's Board is authorized to issue shares of the Company's preferred stock from time to time, in one or more classes or series, without stockholder approval. Prior to the issuance of shares of each series, the Board is required by the General Corporation Law of the State of Delaware ("DGCL") to adopt resolutions and file a Certificate of Designation with the Secretary of State of the State of Delaware, fixing for each such series the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series. Any exercise of the Company's Board of its rights to do so may affect the rights and entitlements of the holders of the Company's common stock as set forth below.

The Company's Board could authorize the issuance of shares of preferred stock with terms and conditions which could have the effect of discouraging a takeover or other transaction which holders of some, or a majority, of such shares might believe to be in their best interests or in which holders of some, or a majority, of such shares might receive a premium for their shares over the then-market price of such shares.

General

Subject to limitations prescribed by the DGCL, the Company's Certificate of Incorporation and the Company's Bylaws ("Bylaws"), the Company's Board is authorized to fix the number of shares constituting each series of preferred stock and the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series, including such provisions as may be desired concerning voting, redemption, dividends, dissolution or the distribution of assets, conversion or exchange, and such other subjects or matters as may be fixed by resolution of the Board. Each series of preferred stock that the Company offers under this prospectus will, when issued, be fully paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

The applicable prospectus supplement(s) will describe the following terms of the series of preferred stock in respect of which this prospectus is being delivered:

- the title and stated value of the preferred stock;
- the number of shares of the preferred stock offered, the liquidation preference per share and the purchase price of the preferred stock;
- the dividend rate(s), period(s) and/or payment date(s) or the method(s) of calculation for dividends;
- whether dividends shall be cumulative or non-cumulative and, if cumulative, the date from which dividends on the preferred stock shall accumulate;
- the procedures for any auction and remarketing, if any, for the preferred stock;
- the provisions for a sinking fund, if any, for the preferred stock;
- the provisions for redemption, if applicable, of the preferred stock;
- any listing of the preferred stock on any securities exchange or market;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock or another series of the Company's preferred stock, including the conversion price (or its manner of calculation) and conversion period;
- the terms and conditions, if applicable, upon which preferred stock will be exchangeable into the Company's debt securities, including the exchange price, or its manner of calculation, and exchange period;

- voting rights, if any, of the preferred stock; a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- whether interests in the preferred stock will be represented by depositary shares;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the Company's affairs;
- any limitations on issuance of any series of preferred stock ranking senior to or on a parity with the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the Company's affairs; and
- any other specific terms, preferences, rights, limitations or restrictions on the preferred stock.

Unless otherwise specified in the prospectus supplement, the preferred stock will, with respect to dividend rights and rights upon liquidation, dissolution or winding up of the Company rank:

- senior to all classes or series of the Company's common stock, and to all equity securities issued by the Company the terms of which specifically provide that such equity securities rank junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of the Company;
- on a parity with all equity securities issued by the Company that do not rank senior or junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of the Company; and
- junior to all equity securities issued by the Company the terms of which do not specifically provide that such equity securities rank on a parity with or junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of the Company (including any entity with which the Company may be merged or consolidated or to which all or substantially all of the Company's assets may be transferred or which transfers all or substantially all of the Company's assets).

As used for these purposes, the term "equity securities" does not include convertible debt securities.

Transfer Agent and Registrar

The transfer agent and registrar for any series of preferred stock will be set forth in the applicable prospectus supplement.

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 registration statement of which this prospectus is a part, as well as the relevant portions of the DGCL.

General

As of the date of this prospectus, the Company has authorized 500 million shares of common stock, par value $0.001 per share. As of August 6, 2019, there were 29,593,535 shares of common stock outstanding.

Voting Rights

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

Dividend Rights

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

Liquidation Rights

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

Other Rights and Preferences

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

Registration Rights

Under our Amended and Restated Investor Rights Agreement, the holders of approximately 7.0 million shares of common stock, or their transferees, have the right to require us to register their shares under the Securities Act so that those shares may be publicly resold, or to include their shares in any registration statement we file, in each case as described below.

Demand Registration Rights

The holders of approximately 7.0 million shares of our common stock (on an as-converted basis), or their transferees, are entitled to certain demand registration rights. The holders of at least 55% of these shares can, on

not more than three occasions, request that we register at least 40% of the shares issued to such holders, or a lesser percentage if the anticipated aggregate offering price, net of underwriting discounts and commissions, would exceed $5,000,000. These registration rights are further subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to use commercially reasonable efforts to effect the registration as soon as practicable.

Piggyback Registration Rights

In the event that we determine to register any of our securities under the Securities Act (subject to certain exceptions), either for our own account or for the account of other security holders, the holders of approximately 7.0 million shares of our common stock (on an as-converted basis), or their transferees, will be entitled to certain "piggyback" registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, the offer and sale of debt securities, or corporate reorganizations or certain other transactions, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include.

Registration on Form S-3

The holders of approximately 7.0 million shares of our common stock (on an as-converted basis), or their transferees, are entitled to certain Form S-3 registration rights. The holders of at least 20% of these shares can make a written request that we register their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least $500,000 net of certain expenses related to the sale of the shares. These stockholders may make an unlimited number of requests for registration on Form S-3, but in no event will we be required to file more than two registrations on Form S-3 within any 12-month period.

Expenses of Registration

We will pay all expenses relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, subject to specified conditions and limitations.

Termination of Registration Rights

The registration rights granted under the Amended and Restated Investor Rights Agreement will terminate, with respect to a particular holder, at the earlier of: (i) such time as that holder and its affiliates may sell all of their shares of common stock pursuant to Rule 144 under the Securities Act during any 90-day period; and (ii) the seven year anniversary of our initial public offering.

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.

- ***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.

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

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

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.

DESCRIPTION OF WARRANTS

General

We may issue warrants for the purchase of our common stock, preferred stock or debt securities. We may issue warrants independently or together with any of our securities. Warrants also may be attached to other securities that we may issue. We may issue warrants in different series under separate warrant agreements or under a single warrant agreement between us and a specified warrant agent described in an applicable prospectus supplement.

The warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants.

As of the date of this prospectus, we have (i) 12,321 warrants to purchase shares of common stock at an exercise price of $15.30 per share, (ii) 531,067 warrants to purchase shares of common stock at an exercise price of $12.60 per share, and (iii) 62,181 warrants to purchase shares of common stock at exercise prices ranging from $5.68 per share to $12.60 per share.

An applicable prospectus supplement will describe the specific terms of any warrants that we issue or offer, including:

- the title of the warrants;
- the aggregate number of warrants;
- the price or prices at which the warrants will be issued;
- the currencies in which the price or prices of the warrants may be payable;
- the designation, amount and terms of our capital stock or debt securities purchasable upon exercise of the warrants;
- the designation and terms of our other securities, if any, that may be issued in connection with the warrants, and the number of warrants issued with each corresponding security;
- if applicable, the date that the warrants and the securities purchasable upon exercise of the warrants will be separately transferable;
- the prices and currencies for which the securities purchasable upon exercise of the warrants may be purchased;
- the date that the warrants may first be exercised;
- the date that the warrants expire;
- the minimum or maximum amount of warrants that may be exercised at any one time;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- information with respect to book-entry procedures, if any;
- the manner in which the warrant agreements and warrants may be modified;
- a discussion of certain federal income tax considerations; and
- any other material terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Exercise of Warrants

Each warrant will entitle the holder to purchase for cash the principal amount of debt securities, preferred stock or common stock at the applicable exercise price set forth in, or determined as described in, the applicable prospectus supplement. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Warrants may be exercised by delivering to the corporation trust office of the warrant agent or any other officer indicated in the applicable prospectus supplement (i) the warrant certificate properly completed and duly executed and (ii) payment of the amount due upon exercise. As soon as practicable following exercise, we will forward the debt securities, preferred stock or common stock purchasable upon exercise. If less than all of the warrants represented by a warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants if the expiration date of the warrants has not occurred. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants. We may, but we will not be required to, permit the exercise of warrants through the delivery of a notice of guaranteed delivery from a bank, a trust company, or a New York Stock Exchange member guaranteeing delivery of (i) payment of the exercise price for the securities for which the warrant is being exercised, and (ii) a properly completed and executed warrant certificate. The notice of guaranteed delivery must be received by the warrant agent before the expiration of the warrants, and the warrant agent will not honor a notice of guaranteed delivery unless a properly completed and executed warrant certificate and full payment for the securities being purchased are received by the warrant agent by the close of business on the third business day after the expiration time of the warrants.

Governing Law

Unless we provide otherwise in an applicable prospectus supplement, the warrants and warrant agreements, and any claim, controversy or dispute arising under or related to the warrants or warrant agreements, will be governed by and construed in accordance with the laws of the State of New York.

Enforceability of Rights by Holders of Warrants

Each warrant agent, if any, will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

DESCRIPTION OF RIGHTS

We may issue rights to purchase shares of our common stock, preferred stock, or warrants in one or more series. Rights may be issued independently or together with any other offered security and may or may not be transferable by the person purchasing or receiving the subscription rights. In connection with any rights offering to our stockholders, we may enter into a standby underwriting arrangement with one or more underwriters pursuant to which the underwriters will purchase any of the offered securities remaining unsubscribed after the expiration of the rights offering. In connection with a rights offering to our stockholders, we will distribute certificates evidencing the rights and an applicable prospectus supplement to our stockholders on the record date that we set for receiving rights in the rights offering. An applicable prospectus supplement will describe the following terms of rights in respect of which this prospectus is being delivered:

- the title of the rights;
- the securities for which the rights are exercisable;
- the exercise price for the rights;
- the date of determining the security holders entitled to the rights distribution;
- the number of the rights issued to each security holder;
- the extent to which the rights are transferable;
- if applicable, a discussion of the material United States federal income tax considerations applicable to the issuance or exercise of the rights;
- the date on which the right to exercise the rights shall commence, and the date on which the rights shall expire (subject to any extension);
- the conditions to completion of the rights offering;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the rights;
- the extent to which the rights include an over-subscription privilege with respect to unsubscribed securities;
- if applicable, the material terms of any standby underwriting or other purchase arrangement that we may enter into in connection with the rights offering; and
- any other terms of the rights, including terms, procedures and limits relating to the exchange or exercise of the rights.

Each right will entitle the holder to purchase an amount of securities for cash, at the exercise price. Rights may be exercised at any time up to the close of business on the expiration date of the rights. After the close of business on the expiration date, all unexercised rights will become void. The manner in which rights may be exercised will be described in an applicable prospectus supplement. We may, but are not be required to, permit the exercise of rights through the delivery of a notice of guaranteed delivery from a bank, a trust company, or a New York Stock Exchange member guaranteeing delivery of (i) payment of the exercise price for the securities for which the rights are being exercised, and (ii) a properly completed and executed rights certificate. The notice of guaranteed delivery must be received by the rights agent before the expiration of the rights, and the rights agent will not honor a notice of guaranteed delivery unless a properly completed and executed rights certificate and full payment for the securities being purchased are received by the rights agent by the close of business on the third business day after the expiration time of the rights. Upon receipt of payment and the proper completion and due execution of the rights certificate at the designated office of the rights agent or any other office indicated in an applicable prospectus supplement, we or the transfer agent will forward, as soon as practicable, the securities purchased upon the exercise of the rights. We may determine to offer any unsubscribed offered securities directly to persons other than stockholders, to or through agents, underwriters or dealers or through a combination of the methods, including pursuant to standby underwriting arrangements, as set forth in an applicable prospectus supplement.

DESCRIPTION OF UNITS

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in an applicable prospectus supplement. The terms of any units offered under an applicable prospectus supplement may differ from the terms described below. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference to reports that we file with the SEC, the form of unit agreement that describes the terms of the series of units we are offering, and any supplemental agreements, before the issuance of the related series of units. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we sell under this prospectus, as well as the complete unit agreement and any supplemental agreements that contain the terms of the units.

General

We may issue units comprised of one or more debt securities, common stock, preferred stock, warrants and/or units in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We will describe in an applicable prospectus supplement the terms of the series of units, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those described under “Description of Preferred Stock,” “Description of Capital Stock,” “Description of Debt Securities,” “Description of Warrants,” and “Description of Rights” will apply to each unit and to any preferred stock, common stock, debt security, warrant or right included in each unit, respectively.

Issuance in Series

We may issue units in the amounts and in numerous distinct series as we determine.

Enforceability of Rights by Holders of Units

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

Title

We, the unit agent and any of its agents may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purposes and as the person entitled to exercise the rights attaching to the units, despite any notice to the contrary.

EXPERTS

The consolidated financial statements of electroCore, Inc. Subsidiaries and Affiliate as of December 31, 2018 and 2017, and for each of the years in the two-year period ended December 31, 2018, have been incorporated by reference herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

LEGAL MATTERS

If and when the securities being registered hereunder are issued, the validity of such issuance will be passed upon for the Company by Dentons US LLP, New York, New York.

WHERE YOU CAN FIND MORE INFORMATION

The Company files annual, quarterly and periodic reports, proxy statements and other information with the SEC. You may read and copy any materials that the Company files with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of the Company's SEC filings are also available to the public from the SEC's Website at www.sec.gov. The Company makes available free of charge its annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please contact the Corporate Secretary at the following address or telephone number: electroCore, Inc., 150 Allen Road, Suite 201, Basking Ridge, New Jersey 07920, Attention: Corporate Secretary; (973) 290-0097. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

The Company maintains its website at www.electrocore.com. The Company's website and the information contained therein or connected thereto are not incorporated into this Registration Statement.

The Company has filed with the SEC a registration statement on Form S-3 under the Securities Act relating to the securities the Company is offering by this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to the Company and the Company's securities. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, the Company refers you to the copy of that contract or document filed as an exhibit to the registration statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows the Company to "incorporate by reference" the information the Company files with them, which means that the Company can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that the Company files later with the SEC will automatically update and supersede this information. The Company incorporates by reference the documents filed with SEC listed below:

- The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 28, 2019.
- The Company's Quarterly Reports on Form 10-Q filed with the SEC on May 15, 2019 and August 14, 2019.
- The Company's Current Reports on Form 8-K and amendment to Current Report on Form 8-K, filed with the SEC on May 30, 2019, June 4, 2019, June 7, 2019, June 10, 2019 and July 15, 2019.
- The description of the Company's capital stock is incorporated herein by reference to the description included under the caption "Description of Capital Stock" of the prospectus included in the Registration Statement on Form S-1 (File No. 333-225084) filed by the Company with the SEC on June 11, 2018.

In addition, all documents subsequently filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934, as amended, prior to the filing of a post-effective amendment which indicates that all securities offered have been sold or which deregisters all securities then remaining unsold, shall be deemed to be incorporated by reference in this Registration Statement and to be a part hereof from the date of filing of such documents. However, any documents or portions thereof, whether specifically listed above or filed in the future, that are not deemed "filed" with the Commission, including without limitation any information furnished pursuant to Item 2.02 or 7.01 of Form 8-K or certain exhibits furnished pursuant to Item 9.01 of Form 8-K, shall not be deemed to be incorporated by reference in this Registration Statement.

Any statement in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for the purposes of this Registration Statement to the extent that a statement contained herein or in any other subsequently filed document which also is incorporated or deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement.

electroCore®

Up to $25,000,000 of Common Stock and
692,514 Shares of Common Stock

PROSPECTUS
SUPPLEMENT

The date of this prospectus supplement is March 30, 2020