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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED March 31, 2020

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 001-38538

electroCore, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**20-3454976**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

150 Allen Road, Suite 201, Basking Ridge, NJ 07920
(Address of principal executive offices, including zip code)

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ECOR	The Nasdaq Global Select Market

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

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

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

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

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

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

As of May 13, 2020, the registrant had 35,851,990 shares of common stock outstanding.

PART I. FINANCIAL INFORMATION

REFERENCES TO ELECTROCORE

In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires, references to the "Company," "electroCore," "we," "us" and "our" refer to electroCore, Inc. a Delaware corporation, and its subsidiaries and affiliate.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 report 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, or 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) risks and uncertainties related to the impact of the COVID-19 pandemic on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate the COVID-19 pandemic, such as travel bans, shelter in place orders and third-party business closures and resource allocations, manufacturing and supply chains and patient access to commercial products; our ability to execute our business continuity as well as our operational and budget plans in light of the COVID-19 pandemic, and (ii) those included in our Annual Report on Form 10-K dated December 31, 2019, filed with the SEC described under "Risk Factors" and in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Quarterly Report and elsewhere in this Quarterly Report on Form 10-Q. Furthermore, such forward-looking statements speak only as of the date of this report. 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.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Balance Sheets

	March 31, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 15,620,496	$ 13,563,791
Marketable securities	—	10,495,350
Accounts receivable, net	272,044	496,140
Inventories, net	664,371	890,992
Prepaid expenses and other current assets	838,735	1,087,111
Total current assets	17,395,646	26,533,384
Inventories, non-current	6,247,439	6,020,180
Property and equipment, net	316,706	345,236
Operating lease right of use assets	1,336,508	1,430,641
Other assets	1,067,965	1,132,238
Total assets	$ 26,364,264	$ 35,461,679
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,646,414	$ 5,208,979
Accrued expenses	3,186,324	3,337,379
Note payable	—	111,878
Current portion of operating lease liabilities	514,917	486,445
Total current liabilities	7,347,655	9,144,681
Noncurrent liabilities:		
Operating lease liabilities	1,282,827	1,419,880
Total liabilities	8,630,482	10,564,561
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, par value $0.001 per share; 10,000,000 shares authorized at March 31, 2020 and December 31, 2019; 0 issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common Stock, par value $0.001 per share; 500,000,000 shares authorized at March 31, 2020 and December 31, 2019; 30,421,427 issued and outstanding at March 31, 2020 and 29,835,183 shares issued and outstanding at December 31, 2019	30,422	29,835
Additional paid-in capital	108,496,344	107,752,066
Accumulated deficit	(91,438,447)	(83,479,098)
Accumulated other comprehensive income/(loss)	9,853	(41,295)
Total stockholders' equity	17,098,172	24,261,508
Noncontrolling interest	635,610	635,610
Total equity	17,733,782	24,897,118
Total liabilities and stockholders' equity	$ 26,364,264	$ 35,461,679

See accompanying notes to unaudited consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Operations
(Unaudited)

	Three months ended March 31,	
	2020	**2019**
Net sales	$ 733,771	$ 409,601
Cost of goods sold	298,115	157,791
Gross profit	435,656	251,810
Operating expenses:		
Research and development	1,523,114	3,459,823
Selling, general and administrative	6,560,726	11,002,999
Restructuring and other severance related charges	365,000	—
Total operating expenses	8,448,840	14,462,822
Loss from operations	(8,013,184)	(14,211,012)
Other (income)/expense		
Interest and other income, net	(62,976)	(366,174)
Other expense	9,141	16,692
Total other (income)/expense	(53,835)	(349,482)
Loss before income taxes	(7,959,349)	(13,861,530)
Provision for income taxes	—	—
Net loss from operations	$ (7,959,349)	$ (13,861,530)
Net loss per share of common stock - Basic and Diluted (see Note 14)	$ (0.27)	$ (0.47)
Weighted average common shares outstanding - Basic and Diluted (see Note 14)	29,774,226	29,319,318

See accompanying notes to unaudited consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three months ended March 31,	
	2020	**2019**
Net loss from operations	$ (7,959,349)	$ (13,861,530)
Other comprehensive income:		
Foreign currency translation adjustment	45,322	43,575
Unrealized gains on securities, net of taxes as applicable	5,826	40,138
Other comprehensive income	51,148	83,713
Comprehensive loss	$ (7,908,201)	$ (13,777,817)

See accompanying notes to unaudited consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

	Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	Total stockholders' equity	Noncontrolling interest	Total equity
	Shares	Amount						
Balances as of December 31, 2018	29,450,035	$ 29,450	$ 103,791,013	$ (38,331,215)	$ 60,843	65,550,091	$ 635,610	$ 66,185,701
Net loss	—	—	—	(13,861,530)	—	(13,861,530)	—	(13,861,530)
Other comprehensive income	—	—	—	—	83,713	83,713	—	83,713
Issuance of warrants in settlement of lawsuit	—	—	16,692	—	—	16,692	—	16,692
Issuance of stock related to employee compensation plans, net of forfeitures	183,205	183	(183)	—	—	—	—	—
Stock based compensation	—	—	744,032	—	—	744,032	—	744,032
Balances as of March 31, 2019	29,633,240	$ 29,633	$ 104,551,554	$ (52,192,745)	$ 144,556	$ 52,532,998	$ 635,610	$ 53,168,608
Balances as of December 31, 2019	29,835,183	$ 29,835	$ 107,752,066	$ (83,479,098)	$ (41,295)	$ 24,261,508	$ 635,610	$ 24,897,118
Net loss	—	—	—	(7,959,349)	—	(7,959,349)	—	(7,959,349)
Other comprehensive income	—	—	—	—	51,148	51,148	—	51,148
Equity financing commitment fee*	461,676	462	(462)	—	—	—	—	—
Issuance of stock related to employee compensation plans, net of forfeitures	124,568	125	(125)	—	—	—	—	—
Share based compensation	—	—	744,865	—	—	744,865	—	744,865
Balances as of March 31, 2020	30,421,427	$ 30,422	$ 108,496,344	$ (91,438,447)	$ 9,853	$ 17,098,172	$ 635,610	$ 17,733,782

* Reflects commitment shares issued in accordance with the Company's equity facility purchase agreement with Lincoln Park Capital. For additional information see Note 13. Stock Purchase Agreement

See accompanying notes to unaudited consolidated financial statements

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Cash Flows
(Unaudited)

	Three months ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss from operations	$ (7,959,349)	$ (13,861,530)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	744,865	744,032
Depreciation and amortization	97,419	25,522
Amortization of marketable securities discount	1,176	(200,302)
Cloud computing arrangement implementation costs	—	(618,044)
Net noncash lease expense	(21,581)	117,579
Noncash portion of litigation settlement	—	16,692
Other	10,937	43,343
Changes in operating assets and liabilities:		
Accounts receivable, net	224,096	(20,736)
Inventories	(638)	(1,639,862)
Prepaid expenses and other current assets	238,376	830,406
Accounts payable	(1,562,615)	(719,463)
Accrued expense and other current liabilities	(151,055)	(1,117,793)
Net cash used in operating activities	(8,378,369)	(16,400,156)
Cash flows from investing activities:		
Purchase of marketable securities	—	(12,110,420)
Proceeds from maturities of marketable securities	10,500,000	27,901,000
Purchases of property and equipment	—	(37,318)
Net cash provided by investing activities	10,500,000	15,753,262
Cash flows from financing activities:		
Repayments of note payable	(111,878)	–
Net cash used in financing activities	(111,878)	-
Effect of changes in exchange rates on cash and cash equivalents	46,952	396
Net increase/(decrease) in cash and cash equivalents	2,056,705	(646,498)
Cash and cash equivalents – beginning of period	13,563,791	7,600,284
Cash and cash equivalents – end of period	$ 15,620,496	$ 6,953,786
Supplemental schedule of noncash activity:		
Prepaid lease payments included in right of use assets	$ —	$ 93,261
Capitalized cloud computing arrangement costs included in accrued expenses and other liabilities	$ —	$ 167,798

See accompanying notes to unaudited consolidated financial statements.

Note 1. The Company

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

electroCore, headquartered in New Jersey, has two wholly owned subsidiaries: electroCore Germany GmbH, and electroCore UK Ltd. Effective April 30, 2020, the Company has ceased its operations in Germany. In addition, an affiliate, electroCore (Aust) Pty Limited, or electroCore Australia, is subject to electroCore's control on a basis other than voting interests and is a variable interest entity, or VIE, for which electroCore is the primary beneficiary.

Note 2. Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements were prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") and with instructions to Form 10-Q and Article 10 of Regulation S-X under the Securities Exchange Act of 1934. In the opinion of management, the Company has made all necessary adjustments, which include normal recurring adjustments necessary for a fair presentation of the Company's consolidated financial position and results of operations for the interim periods presented. Certain information and disclosures normally included in the annual consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2020. The results for the three months ended March 31, 2020 are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

(b) Principles of Consolidation

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

(c) Use of Estimates

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

(d) Credit Losses on Financial Instruments

In June 2016, the FASB issued guidance on the measurement of credit losses which requires measurement and recognition of expected credit losses for financial assets, including trade receivables held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The method to determine a loss is different from the existing guidance, which requires a credit loss to be recognized when it is probable. The guidance is effective beginning January 1, 2020. The Company adopted this guidance and determined the impact was immaterial on the consolidated to the financial statements.

(e) Fair Value Measurement

In August 2018, the FASB issued guidance which modifies the disclosure requirements for fair value measurements. The guidance is effective for the year ended December 31, 2020. The Company adopted this guidance which was properly reflected in the consolidated financial statements. There were no material changes to the prior disclosure.

(f) Recent Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued an update to simplify the accounting for income taxes and improve consistent application by clarifying or amending existing guidance. This guidance is effective for the year ended December 31, 2021. The Company does not expect this guidance to have a material impact on its consolidated financial statements upon adoption.

Note 3. Risks and Uncertainties

Liquidity Risks

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

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

The Company incurred net losses of $8.0 million and $13.9 million for the three months ended March 31, 2020 and March 31, 2019, respectively The Company incurred net losses of $45.1 million and $55.8 million for the years ended December 31, 2019 and 2018, respectively. As of March 31, 2020, its accumulated deficit was $91.4 million.

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

In April 2020, the Company received aggregate proceeds of approximately $5.0 million from sales of common stock to Lincoln Park and a private placement transaction to certain affiliates and existing shareholders of the Company, including some members of the Company’s Board of Directors.

In May 2020, the Company entered into a loan for approximately $1.4 million under the Paycheck Protection Program (“PPP”) under the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”). Under the terms of the CARES Act, PPP loan recipients can be granted forgiveness for all or a portion of the loan granted under the PPP, with such forgiveness to be determined, subject to limitations, based on the use of the loan proceeds for payment of certain expenses and loan recipients maintaining their payroll levels over certain required thresholds under the PPP. The terms of any forgiveness also may be subject to further requirements in any regulations and guidelines the Small Business Administration (“SBA”) may adopt. No assurance can be provided that the Company will obtain forgiveness of the Note in whole or in part. Official guidance and interpretations of the requirements of the program have been limited and have been changing over time. Despite the Company’s good-faith belief that it properly satisfied all eligibility requirements for the PPP loan, there has been increasing scrutiny of public companies that received loans, and there can be no assurance that the Company will not become subject to regulatory or other scrutiny, including a request or requirement for re-payment of some or all of the loan.

In May 2020, the Company received proceeds of approximately $1.2 million from a sale of state tax NOLs under the New Jersey Technology Business Tax Certificate Transfer (NOL) Program.

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

Even if the Company is not required to curtail its activities sooner, its ability to execute its operating plan beyond the first quarter of 2021 depends on its ability to increase revenue, reduce operating expenses and obtain additional funding through the sale of equity and or debt securities, a strategic transaction or otherwise. There is no assurance that the Company will generate sufficient funding through its operating results or sale of securities, raising substantial doubt about the Company's ability to continue as a going concern within one year of the date these financial statements are issued. The accompanying financial statements do not include any adjustment that might result from the outcome of this uncertainty.

Concentration of Revenue Risks

The Company earns a significant amount of its revenue (i) in the U.S. from the Department of Veterans Affairs and Department of Defense pursuant to its qualifying contract under the Federal Supply Schedule and open market sales to individual Department of Veterans Affairs facilities and (ii) in the United Kingdom from the National Health Service. Net sales from these two channels represented 95% and 30% of the Company's net sales for the three months ended March 31, 2020 and 2019, respectively.

Foreign Currency Exchange Risks

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

COVID-19 Risks and Uncertainties

The Company is monitoring the impact of the COVID-19 pandemic on all aspects of its business and geographies, including how it will impact business partners. While the Company began to experience disruptions during the three months ended March 31, 2020 from the COVID-19 pandemic, it is unable to predict the full impact that the COVID-19 pandemic may have on its financial condition, results of operations and cash flows due to numerous uncertainties. These uncertainties include the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. The outbreak of COVID-19 in many countries, including the United States, has significantly adversely impacted global economic activity and has contributed to significant volatility and negative pressure in financial markets.

In addition, because the COVID-19 pandemic affected, among other things, our access to prescribing physicians and their access to headache patients, on March 23, 2020 we suspended our earlier full-year revenue guidance until we could better understand the trajectory of our business, as well as announcing a reduction in our activities, and adjusting our cash runway expectations in response to the potential adverse impact cause by the COVID-19 pandemic. Compared to our earlier expectations, we believe that our results for the quarter ended March 31, 2020 reflect a negative impact from, among other things, the global pandemic. Moreover, our expectations for the remainder of 2020 have also been adversely affected by both the uncertainty and potential negative impact of the global pandemic, which we believe may also have had an adverse effect on our access to debt and equity capital markets. Depending upon the duration and severity of the pandemic, the continuing effect on our results and outlook over the long term remains somewhat uncertain.

Note 4. Revenue Recognition

Geographical Net Sales

The following table presents net sales disaggregated by geographic area:

	For the three months ended March 31,	
	2020	**2019**
Geographic Market		
United States	$ 457,559	$ 276,465
United Kingdom	245,466	90,584
Germany	30,746	35,836
Other	-	6,716
Total Net Sales	$ 733,771	$ 409,601

Performance Obligations

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

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

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

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

Contract Balances

The Company generally invoices the customer and recognizes revenue once its performance obligations are satisfied, at which point payment is unconditional. Accordingly, under ASC 606, the Company's contracts with customers did not give rise to contract assets or liabilities during the three months ended March 31, 2020 and 2019.

Note 5. Cash, Cash Equivalents and Marketable Securities

The following tables summarize the Company's cash, cash equivalents and marketable securities as of March 31, 2020 and December 31, 2019.

As of March 31, 2020

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 15,614,320	$ 6,176	$ —	$ 15,620,496

As of December 31, 2019

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

Note 6. Fair Value Measurements

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

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

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

		Fair Value Hierarchy		
March 31, 2020	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash and cash equivalents	$ 15,620,496	$ 15,620,496	$ —	$ —
Total	$ 15,620,496	$ 15,620,496	$ —	$ —
December 31, 2019				
Assets				
Cash and cash equivalents	$ 13,563,791	$ 13,563,791	$ —	$ —
Marketable Securities:				
U.S. treasury bonds	10,495,350	10,495,350	—	—
Total	$ 24,059,141	$ 24,059,141	$ —	$ —

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the three months ended March 31, 2020 and year ended December 31, 2019. The carrying amount of the Company's receivables and payables approximate their fair values due to their short maturities.

Note 7. Inventories

As of March 31, 2020 and December 31, 2019, inventories consisted of the following:

	March 31, 2020	December 31, 2019
Raw materials	$ 1,984,532	$ 1,065,345
Work in process	4,582,175	5,314,763
Finished goods	345,103	531,064
Total inventory	6,911,810	6,911,172
Less: noncurrent	(6,247,439)	(6,020,180)
Total - current	$ 664,371	$ 890,992

As of March 31, 2020 and December 31, 2019, the Company's reserves for obsolete inventory totaled $287,544. The Company records charges for obsolete inventory in cost of goods sold. Noncurrent inventory is comprised of approximately $1.8 million of raw materials and $4.4 million of work in process.

Note 8. Property and Equipment – Net

Property and equipment, net, as of March 31, 2020 and December 31, 2019 consisted of the following:

	March 31, 2020	December 31, 2019
Machinery and equipment	$ 393,154	$ 393,154
Furniture and fixture	309,190	310,820
Computer equipment	20,783	20,783
Leasehold Improvements	8,880	8,880
Property and equipment - gross	732,007	733,637
Less accumulated depreciation and amortization	(415,301)	(388,401)
Property and equipment - net	$ 316,706	$ 345,236

Property and equipment depreciation and amortization expense for the three months ended March 31, 2020 and 2019 was $26,900 and $25,522, respectively.

Note 9. Leases

For the three months ended March 31, 2020 and 2019, the Company recognized lease expense of $119,650 and $199,654, respectively. This expense does not include non-lease components associated with the lease agreements as the Company elected not to include such charges as part of the lease expense.

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

Supplemental Balance Sheet Information for Operating Leases

	March 31, 2020	December 31, 2019
Operating leases:		
Operating lease right of use assets	$ 1,336,508	$ 1,430,641
Operating lease liabilities:		
Current portion of operating lease liabilities	514,917	486,445
Noncurrent operating lease liabilities	1,282,827	1,419,880
Total operating lease liabilities	$ 1,797,744	$ 1,906,325
Weighted average remaining lease term (in years)	5.8	5.9
Weighted average discount rate	13.75%	13.75%

Supplemental Statement of Cash Flows Information for Operating Leases

	Three months ended	
	March 31, 2020	March 31, 2019
Noncash lease expense	$ 87,000	$ 70,315
Change in operating lease liabilities	$ (108,581)	$ 47,264

Future minimum lease payments under non-cancellable operating leases as of March 31, 2020:

Remainder of 2020	$ 487,694
2021	743,818
2022	337,254
2023	142,892
2024 and thereafter	822,304
Total future minimum lease payments	2,533,962
Less: Amounts representing interest	(736,218)
Total	$ 1,797,744

Note 10. Cloud Computing Arrangement

In 2018, the Company entered into a contract to obtain a cloud computing arrangement (“CCA”). In accordance with ASU 2018-15, the implementation costs incurred in the CCA are deferred and recognized as other assets and are amortized to expense over the noncancelable term of the arrangement. The implementation of this CCA was completed on June 30, 2019. Beginning July 1, 2019, the Company went live with the cloud computing Enterprise Resource Planning system and all future related costs are expensed as incurred. In July 2019, the Company began amortizing the related deferred costs over the remaining period of the noncancelable arrangement. Amortization costs for the three months ended March 31, 2020 were $70,519. As of March 31, 2020, and December 31, 2019 the net book value of the CCA was $1,010,776 and $1,081,284 respectively.

Note 11. Accrued Expenses

Accrued expenses as of March 31, 2020 and December 31, 2019 consisted of the following:

	March 31, 2020	December 31, 2019
Accrued professional fees	533,793	1,255,494
Accrued bonuses	759,308	804,082
Other accrued expenses	1,893,223	1,277,803
	$ 3,186,324	$ 3,337,379

Note 12. Note Payable

Finance and Security Agreement

On July 1, 2019, the Company entered into a Commercial Insurance Premium Finance and Security Agreement, or the Financing Agreement. The Financing Agreement provided for a single borrowing by the Company of $807,347, with a seven-month term, and an annual interest rate of 2.99%. The proceeds from this transaction were used to partially fund the premiums due under some of the Company's insurance policies. The amounts payable were secured by the Company's rights under such policies. During the three months ended March 31, 2020, the Company recognized $4,609 in interest expense. All borrowings were fully repaid as of March 31, 2020.

Note 13. Stock Purchase Agreement

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

In consideration for entering into the purchase agreement with Lincoln Park, the Company issued an aggregate of 461,676 shares of common stock to Lincoln Park as a commitment fee. In addition, the Company will issue to Lincoln Park an aggregate of 230,838 additional shares of common stock as a further commitment fee based on the first $5,000,000 of shares of common stock issued to Lincoln Park under the Purchase Agreement as Purchase Shares (as such term is defined in the purchase agreement with Lincoln Park). The Company will not receive any cash proceeds from the issuance of any of the foregoing commitment shares.

The net proceeds under the purchase agreement to the Company will depend on the frequency and prices at which shares of common stock are sold to Lincoln Park. Actual sales of shares of common stock to Lincoln Park under the purchase agreement and the amount of such net proceeds will depend on a variety of factors, including market conditions, the trading price of the common stock and determinations by the Company as to other available and appropriate sources of funding for the Company. The Company expects to use the proceeds from this agreement for general corporate purposes and working capital. In April 2020, the Company sold 3,200,000 shares of the Company's common stock under its purchase agreement with Lincoln Park, resulting in aggregate proceeds of approximately $3.2 million to the Company. -See Note 21. Subsequent Events

Note 14. Net Loss Per Share

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

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

	March 31,	
	2020	**2019**
Outstanding stock options	3,808,563	2,901,970
Nonvested restricted stock and unit awards	1,094,825	1,608,434
Stock purchase warrants	62,181	62,181

Note 15. Variable Interest Entity

As discussed in Note 1, electroCore is the primary beneficiary of electroCore Australia. In return for a 50% interest in such entity, electroCore has contributed certain intellectual property rights; all rights to distribute, market and sell specified products in Australia and New Zealand; and other rights outlined in the shareholders' deed of electroCore Australia. In addition, electroCore can also appoint two of electroCore Australia's four directors and can exercise significant influence

over it. This along with the fact that electroCore is electroCore Australia's only supplier causes electroCore, for accounting purposes, to be beneficiary of electroCore Australia. The activities related to electroCore Australia are not material to the consolidated financial statements.

Note 16. Income Taxes

There is no provision for income taxes for the three months ended March 31, 2020 and 2019. The Company has incurred U.S. operating losses since inception and has not incurred any other income taxes. On March 27, 2020 the President of the United States signed into law the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. The CARES Act, among other things, includes certain tax provisions for individuals and corporations; however, the benefits do not impact the Company's current tax provision.

Note 17. Stock Based Compensation

The following table presents a summary of stock options granted:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2020	3,131,266	$ 8.53	8.9	*
Granted	861,257	1.50		
Exercised	—	—		
Cancelled	(183,960)	8.86		
Outstanding, March 31, 2020	3,808,563	$ 8.91	8.7	*
Exercisable, March 31, 2020	1,819,443	$ 12.08	8.3	*

** de minimis*

The intrinsic value is calculated as the difference between the fair market value at March 31, 2020 and the exercise price per share of the stock options. The options generally vest over a four-year period.

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

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2020	127,505	$ 8.09
Granted	—	—
Vested	(7,836)	15.00
Cancelled	(11,049)	9.65
Nonvested, March 31, 2020	108,620	$ 7.43

In general, restricted stock awards vest over four years.

The following table presents a summary of restricted and deferred stock units, or Stock Units granted:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested, January 1, 2020	1,241,493	$ 2.86
Granted	94,640	1.15
Vested	(135,617)	1.95
Cancelled	(214,311)	4.27
Nonvested, March 31, 2020	986,205	$ 2.51

In general, Stock Units vest over two to four years.

The Company recognized stock compensation for its equity awards as follows:

	Three months ended	
	March 31, 2020	March 31, 2019
Selling, general and administrative	$ 547,090	$ 438,761
Research and development	$ 186,599	276,556
Cost of goods sold	$ 11,176	28,715

Total unrecognized compensation cost related to unvested awards as of March 31, 2020 was $6.4 million and is expected to be recognized over the next 2.6 years.

Valuation Information for Stock-Based Compensation

The fair value of each stock option award during the three months ended March 31, 2020 and 2019 was estimated on the date of grant using the Black-Scholes model. Expected volatility was based on historical volatility of the Company's common stock. The risk-free interest rate was based on the average U.S. Treasury rate that most closely resembles the expected life of the related award. The expected term of the award was calculated using the simplified method. No dividend was assumed as the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

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

	Three months ended March 31, 2020	Three months ended March 31, 2019
Fair value at grant date	$ 1.27	$ 4.89
Expected volatility	113.4%	84.6%
Risk-free interest rate	1.4%	2.4%
Expected holding period, in years	6.1	5.5
Dividend yield	—	—

Note 18. Employee Stock Purchase Plan

On January 1, 2019, the Company adopted the 2019 Employee Stock Purchase Plan, or the ESPP, which was approved by stockholder vote at the 2019 Annual Meeting of Stockholders held on June 7, 2019. The plan provided eligible employees of the Company with an opportunity to purchase common stock of the Company through accumulated payroll deductions, which were included in other current liabilities until they are used to purchase Company shares. On January 1, 2020 the Company terminated the ESPP. The common stock issuable in respect of the second bi-annual period under the plan were issued to eligible participating employees during the first quarter of 2020.

No expense was recognized for the ESPP for the quarters ended March 31, 2020 and 2019.

Note 19. Restructuring and Other Severance Related Payments

In January 2020, the Company entered into a separation agreement with a former officer. This agreement requires a severance payment of $190,000 over a six-month period.

In January 2020, the Company entered into an agreement with a new employee that requires the unconditional payment of $175,000, in lieu of future severance. Payment is to be made in equal monthly installments over a fourteen-month period.

During the three months ended March 31, 2020, the Company recorded a charge of $365,000 in connection with these agreements. This expense is classified as restructuring and other severance related expense on its consolidated statements of operations.

As of March 31, 2020, $264,167 is owed by the Company under these agreements. This amount is classified under accrued liabilities on its balance sheet.

Note 20. Commitments and Contingencies

Stockholders Litigation

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

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

In the Turnofsky case, on November 25, 2019 several plaintiffs and their counsel moved to be selected as lead plaintiff and lead plaintiff's counsel. On April 24, 2020, the Court granted the motion of Carole Tibbs and the firm Bragar, Eagel & Squire, P.C. The Priewe case was voluntarily dismissed on February 19, 2020.

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

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

Settlement Agreement

In January 2019, the Company settled a dispute with one of its former advisors, Madison Global Partners, who had filed a complaint against the Company in the Supreme Court of the State of New York, County of New York (Index No. 652329/2018). As part of that settlement, the Company paid Madison Global $325,000 and issued to Madison Global and its representatives warrants to purchase in the aggregate 62,181 shares of its common stock at prices ranging from $5.68 per share to $12.60 per share. In January 2019, 5,192 warrants with an exercise price of $5.68 were issued and the expense was recognized. All other amounts were accrued in prior accounting periods. The warrants issued are shown in the following table:

# Warrants		Exercise Price	Expiration Dates
8,576	$	8.86	April 1, 2021
22,253	$	5.68	March 30, 2022
17,066	$	12.60	June 30, 2022
14,286	$	12.60	August 31, 2022

Note 21. Subsequent Events

Sales of Stock

In April 2020, the Company sold 3,200,000 shares of the Company's common stock under its purchase agreement with Lincoln Park, resulting in aggregate proceeds of approximately $3.2 million to the Company. In connection with this sale, the Company issued an additional 149,454 shares of its common stock to Lincoln Park as a commitment fee under the purchase agreement.

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

On May 14, 2020, the Company entered into a Securities Purchase Agreement, or the Agreement, with its legal counsel pursuant to which the Company agreed to issue 1,564,345 shares of common stock, at a purchase price of $0.99 per share. Upon issuance of the shares, certain outstanding financial obligations of the Company owed to its legal counsel will be deemed paid and satisfied in full. The Agreement contains customary representations, warranties and covenants of the Company and its legal counsel, and the closing of the Agreement is subject to customary closing conditions. In addition, the Company's legal counsel was granted customary registration rights.

Loan Under the Paycheck Protection Program

On May 4, 2020, the Company received proceeds of $1,409,300 in connection with a promissory note, or the Note, entered into with Citibank, N.A., evidencing an unsecured loan, or the Loan, under the Paycheck Protection Program, or the PPP. The PPP is a program of the U.S. Small Business Administration, or the SBA, established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). Under the PPP, the proceeds of the Loan may be used to pay payroll and make certain covered interest payments, lease payments and utility payments, or Qualifying Expenses. The Company intends to use the entire Loan amount for Qualifying Expenses under the PPP.

The interest rate on the Loan is 1.0% per annum. The Note matures on May 2, 2022. On December 2, 2020, or the First Payment Date, the Company is required to pay all accrued interest under the Loan that is not forgiven in accordance with the terms of the PPP. Additionally, on the First Payment Date and on the second day of each month thereafter until May 2, 2022, the Company must make equal monthly payments of the amount of principal under the Loan that is not forgiven in

accordance with the terms of the PPP and related accrued interest thereon. The Note contains events of default and other conditions customary for a Note of this type.

Under the terms of the CARES Act, PPP loan recipients can be granted forgiveness for all or a portion of the loan granted under the PPP, with such forgiveness to be determined, subject to limitations, based on the use of the loan proceeds for payment of Qualifying Expenses and the Company maintaining its payroll levels over certain required thresholds under the PPP. The terms of any forgiveness also may be subject to further requirements in any regulations and guidelines the SBA may adopt. No assurance can be provided that the Company will obtain forgiveness of the Note in whole or in part. Official guidance and interpretations of the requirements of the program have been limited and have been changing over time. Despite the Company's good-faith belief that it properly satisfied all eligibility requirements for the PPP loan, there has been increasing scrutiny of public companies that received loans, and there can be no assurance that the Company will not become subject to regulatory or other scrutiny, including a request or requirement for re-payment of some or all of the loan.

Sale of New Jersey net operating losses

On May 6, 2020, in connection with the New Jersey Technology Business Tax Certificate Transfer (NOL) Program, the Company received approximately $1.2 million for the sale of approximately $13.9 million of its New Jersey net operating losses.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2019 included in our Annual Report on Form 10-K, filed with the SEC. As discussed in the section titled "Cautionary Note Regarding Forward-Looking Statements," the following discussion and analysis contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those under the caption "Risk Factors" in the aforementioned Annual Report.

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.

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

Recent Developments

On April 2, 2020, we announced that the we had submitted an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) to facilitate the study and clinical use of our gammaCore SapphireTM nVNS therapy, for respiratory symptoms associated with COVID-19.

The EUA includes data from early clinical and non-clinical work that examined the use of our VNS, including non-invasive therapy, in several pilot studies that involved patients with a variety of respiratory disorders. These studies suggest a possible benefit for patients with respiratory distress associated with COVID-19. Additionally, gammaCore's strong safety and tolerability profile suggest that it would be safe to study or use in patients with COVID-19. We have not received any decision from the FDA regarding the EUA.

In April 2020, we terminated our Premium II clinical trial that was being conducted to further support our label expansion into migraine prevention. As a result, there are currently no company-funded studies ongoing.

In April 2020, we received aggregate proceeds of approximately $3.2 million through the sales of our common stock to Lincoln Park Capital Fund, LLC, or Lincoln Park.

In April 2020, we received aggregate proceeds of $1.75 million through the sale of our common stock in a private placement transaction to affiliates and existing shareholders of the Company, including some members of our Board of Directors.

On May 4, 2020, we entered into a loan for approximately $1.4 million under the Paycheck Protection Program.

On May 6, 2020, in connection with the New Jersey Technology Business Tax Certificate Transfer (NOL) Program, we received approximately $1.2 million for the sale of approximately $13.9 million of our New Jersey state tax net operating losses.

On May 14, 2020, we entered into a Securities Purchase Agreement, or the Agreement, with our legal counsel pursuant to which we agreed to issue 1,564,345 shares of common stock, at a purchase price of $0.99 per share. Upon issuance of the shares, certain of our outstanding financial obligations to our legal counsel will be deemed paid and satisfied in full. The Agreement contains customary representations, warranties and covenants of us and its counsel, and the closing of the Agreement is subject to customary closing conditions. In addition, our legal counsel was granted customary registration rights.

Impact of COVID-19

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

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

Results of Operations

Comparison of the three months ended March 31, 2020 to the three months ended March 31, 2019

The following table sets forth amounts from our consolidated statements of operations for the three months ended March 31, 2020 and 2019 with the changes in those items in dollars.

	For the three months ended March 31,		
	2020	2019	Change
		(in thousands)	
Consolidated statements of operations:			
Net sales	$ 733.7	$ 409.6	$ 324.1
Cost of goods sold	298.1	157.8	140.3
Gross profit	435.6	251.8	183.8
Operating expenses			
Research and development	1,523.1	3,459.8	(1,936.7)
Selling, general and administrative	6,560.7	11,003.0	(4,442.3)
Restructuring and other severance related charges	365.0	—	365.0
Total operating expenses	8,448.8	14,462.8	(6,014.0)
Loss from operations	(8,013.2)	(14,211.0)	6,197.8
Other (income)/expense			
Interest and other income, net	(63.0)	(366.2)	303.2
Other	9.1	16.7	(7.6)
Total other (income)/expense	(53.9)	(349.5)	295.6
Loss before income taxes	(7,959.3)	(13,861.5)	5,902.2
Provision for income taxes	—	—	—
Net loss from operations	$ (7,959.3)	$ (13,861.5)	$ 5,902.2

Net Sales

Net sales increased 79% for the three months ended March 31, 2020 compared to the prior year period. The increase of $324,200 is due to increased sales to the Veteran Administration and in the United Kingdom. This increase was partially offset by reduced sales in the U.S. commercial channel.

Gross Profit

Gross profit increased $184,000 for the three months ended March 31, 2020 compared to the prior year period. This increase was due to the increase in net sales. Gross margin was 59% and 61% for the three months ended March 31, 2020 and 2019, respectively. This slight decrease in margin is largely due to the increase in unit labor and overhead, that was previously absorbed by production for our Partners For Coverage program that was terminated in December 2019. In the fourth quarter of 2019, we launched a 93-day product offering at a reduced average sales price per paid month of therapy, which also reduced our gross margin.

Research and Development

Research and development expense decreased by $1.9 million or 56% for the three months ended March 31, 2020 compared to the prior year period. This reduction was primarily due to significant reductions in near-term investment in research and development.

Selling, General and Administrative

Selling, general and administrative expense decreased by $4.4 million or 40% for the three months ended March 31, 2020 compared to the prior year period. This decrease was primarily due to a significant reduction in personnel and non-personnel costs for sales and marketing activities, which was initiated in the second quarter of 2019.

Restructuring and Other Severance Related Expenses

Restructuring and other severance related costs for the three months ended March 31, 2020 consists of severance related expenses in connection with personnel changes in the position of Chief Medical Officer. There was no such expense for the three months ended March 31, 2019.

Cash Flows

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

	For the three months ended March 31,	
	2020	2019
	(in millions)	
Net cash (used in) provided by		
Operating activities	$ (8.4)	$ (16.4)
Investing activities	$ 10.5	$ 15.8
Financing activities	$ (0.1)	$ -

Operating Activities

Net cash used in operating activities was $8.4 million and $16.4 million for the three months ended March 31, 2020 and 2019, respectively. This decrease is primarily due to a decrease in our net loss from operations and less cash being used for the payment of management bonuses in 2020.

Investing Activities

Net cash provided by investing activities was $10.5 million and $15.8 million for the three months ended March 31, 2020 and 2019, respectively. The decrease reflects the decrease in funds received from the maturities of marketable securities.

Financing Activities

Net cash used in financing activities was $0.1 million and $0.0 million for the three months ended March 31, 2020 and 2019, respectively. This change reflects the final payment made on our outstanding note.

Contractual Obligations and Commitments

In the normal course of business, we enter into obligations and commitments that require future contractual payments. The commitments result primarily from lease for office space and leased equipment and purchases of inventory.

There are no material changes to the contractual obligations and commercial commitments, addressed in Note 20 in these quarterly financial statements that were disclosed in the December 31, 2019 audited consolidated financial statements.

Liquidity Outlook

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

Our financial statements have been prepared assuming we will continue as a going concern. We have experienced recurring losses since our inception. We incurred net losses of $8.0 million and $13.9 million for the three months ended March 31, 2020 and March 31, 2019, respectively. As of March 31, 2020, our accumulated deficit was $91.4 million.

At March 31, 2020, we had approximately $15.6 million of cash and cash equivalents.

On March 27, 2020, we entered into a purchase agreement with Lincoln Park pursuant to which we have the right to sell to Lincoln Park shares of common stock having an aggregate value of up to $25,000,000, subject to certain significant limitations of the amount and timing of any such sales due to terms and conditions set forth in the purchase agreement.

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

If we direct Lincoln Park to purchase the maximum number of shares of common stock that we may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, we may direct Lincoln Park to make an "accelerated purchase" of an additional number of shares of common stock which may not exceed the lesser of: (i) 300% of the number of shares purchased pursuant to the corresponding Regular Purchase and (ii) 30% of the total number of shares of the common stock traded during a specified period on the applicable purchase date as set forth in the Purchase Agreement. The purchase price for such shares will be the lesser of 97% of the volume weighted average price of the common stock over a certain portion of the date of sale as set forth in the Purchase Agreement and (ii) the closing sale price of the common stock on the date of sale (an "Accelerated Purchase"). Under certain circumstances and in accordance with the Purchase Agreement, we may direct Lincoln Park to purchase shares in multiple Accelerated Purchases on the same trading day.

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

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of Common stock as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder.

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

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

The Purchase Agreement and Registration Rights Agreement each contain customary representations, warranties, and agreements of us and Lincoln Park, indemnification rights and other obligations of the parties. The Offering of common stock pursuant to the Purchase Agreement will terminate on the date that all shares offered by the Purchase Agreement have been sold or, if earlier, the expiration or termination of the Purchase Agreement. We have the right to terminate the Purchase Agreement at any time, without fee, penalty or cost to us.

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

In April 2020, we received aggregate proceeds of approximately $3.2 million through the sales of our common stock to Lincoln Park.

In April 2020, we received aggregate proceeds of $1.75 million through the sale of our common stock in a private placement transaction to affiliates and existing shareholders of the Company, including members of our Board of Directors.

On May 4, 2020, we entered into a promissory note, or the Note with Citibank, N.A., evidencing an unsecured loan, or the Loan, in the amount of $1,409,300 made to us under the Paycheck Protection Program, or the PPP. The PPP is a program of the U.S. Small Business Administration or the SBA, established under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. Under the PPP, the proceeds of the Loan may be used to pay payroll and make certain covered interest payments, lease payments and utility payments, or Qualifying Expenses. We intend to use the entire Loan amount for Qualifying Expenses under the PPP.

The interest rate on the Loan is 1.0% per annum. The Note matures on May 2, 2022. On December 2, 2020, or the First Payment Date, we are required to pay all accrued interest under the Loan that is not forgiven in accordance with the terms of the PPP. Additionally, on the First Payment Date and on the second day of each month thereafter until May 2, 2022, we must make equal monthly payments of the amount of principal under the Loan that is not forgiven in accordance with the terms of the PPP and related accrued interest thereon. The Note contains events of default and other conditions customary for a Note of this type.

Under the terms of the CARES Act, PPP loan recipients can be granted forgiveness for all or a portion of the loan granted under the PPP, with such forgiveness to be determined, subject to limitations, based on the use of the loan proceeds for payment of Qualifying Expenses and us maintaining our payroll levels over certain required thresholds under the PPP. The terms of any forgiveness also may be subject to further requirements in any regulations and guidelines the SBA may adopt. No assurance can be provided that we will obtain forgiveness of the Note in whole or in part. Official guidance and interpretations of the requirements of the program have been limited and have been changing over time. Despite our good-faith belief that we properly satisfied all eligibility requirements for the PPP loan, there has been increasing scrutiny of public companies that received loans, and there can be no assurance that we will not become subject to regulatory or other scrutiny and a request for re-payment of some or all of the loan.

On May 6, 2020, in connection with the New Jersey Technology Business Tax Certificate Transfer (NOL) Program, we received approximately $1.2 million for the sale of approximately $13.9 million of our New Jersey state tax net operating losses.

We expect to continue to incur substantial negative cash flows from operations for at least the next several years as we commercialize gammaCore. We intend to continue to make targeted investments in building our U.S. commercial infrastructure.

Our expected cash requirements for 2020 and beyond are based on the commercial success of our products and our ability to reduce operating expenses. There are significant risks and uncertainties as to our ability to achieve these operating results, including as a result of the adverse impact on our business from the ongoing COVID-19 pandemic, Due to these risks and uncertainties, we may need to reduce our activities significantly more than our current operating plan and cash flow

projections assume in order to fund operations beyond one year from the date these financials are issued. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and, ultimately, potentially cease operations. These conditions raise substantial doubt about our ability to continue as a going concern.

Even if we are not required to curtail our activities sooner, our ability to execute our operating plan beyond the first quarter of 2021 depends on our ability to increase revenue, reduce operating expenses and obtain additional funding through the sale of equity and or debt securities, a strategic transaction or otherwise. However, these alternatives may not be available to us on attractive terms, or at all. There is no assurance that we will generate sufficient cash flow and funding through our operating results or the sale of securities or from a strategic transaction or otherwise, raising substantial doubt about our ability to continue as a going concern within one year of the date these financial statements are issued. The inability to generate sufficient cash flow or raise funds through the sources discussed above could have a material adverse effect on our business, results of operations, and financial condition, and could require us to reduce or curtail activities, or cease operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

If the U.S. dollar uniformly increased or decreased in strength by 10% relative to the currencies in which our sales were denominated, our net income would have correspondingly increased or decreased by an immaterial amount for the three months ended March 31, 2020.

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

All of the potential changes noted above are based on sensitivity analyses performed on our financial position as of March 31, 2020.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

As required by Rule 13a-15(b) of the Exchange Act, an evaluation as of March 31, 2020 was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures, as of March 31, 2020, were effective for the purposes stated above.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the quarter ended March 31, 2020 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

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

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

In the Turnofsky case, on November 25, 2019 several plaintiffs and their counsel moved to be selected as lead plaintiff and lead plaintiff's counsel. On April 24, 2020, the Court granted the motion of Carole Tibbs and the firm Bragar, Eagel &
Squire, P.C. The Priewe case was voluntarily dismissed on February 19, 2020.
We intend to continue to vigorously defend ourselves in these matters. However, in light of, among other things, the preliminary stage of these litigation matters, we are unable to determine the reasonable probability of loss or a range of potential loss. Accordingly, we have not established an accrual for potential losses, if any, that could result from any unfavorable outcome, and there can be no assurance that these litigation matters will not result in substantial defense costs and/or judgments or settlements that could adversely affect our financial condition.

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

Item 1A.

RISK FACTORS

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

Risks Related to COVID-19

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

The coronavirus pandemic has severely depressed 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, voluntary or mandated closures of travel-related businesses, as well as quarantines, shelter-in-place/stay-at-home and social distancing orders.

This coronavirus pandemic has also impacted, and may continue to impact, our headquarters and warehouses, as well as those of our 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 corporate office as a result of state-imposed restrictions. The coronavirus pandemic may also impact our ability to sell our products and may increase our costs.

The spread of coronavirus has also caused us to modify our business practices (including social distancing practices, requiring non-essential production related team members to work remotely where possible, restricting business travel, cancelling certain events, and limiting visitor access to our facilities), and we may take further actions as may be required by government authorities or that we determine are necessary or advisable. Work-from-home and other measures introduce additional operational risks, including cybersecurity risks, and have affected the way we conduct our business, which could have an adverse effect on our operations. There is no certainty that such measures will be sufficient to mitigate the risks posed by the virus, and illness and workforce disruptions could lead to unavailability of key personnel and harm our ability to perform critical functions. In addition, work-from-home and related business practice modifications present significant challenges to maintaining our corporate culture, including employee engagement and productivity, both during the immediate pandemic crisis and as we make additional adjustments in the eventual transition from it.

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.

The degree to which coronavirus impacts our results will continue to depend on future developments, which are highly uncertain and cannot be predicted, including how quickly and to what extent normal economic and operating conditions can resume, if at all. These uncertainties may result in delays or modifications to our plans, initiatives and results.

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

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

Risk 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 $8.0 million and $13.9 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, our accumulated deficit was $91.4 million. Our prior losses, combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders' deficit and working capital.

To become and remain profitable, we must successfully commercialize our 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 future 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 March 31, 2020, we had cash and cash equivalents of $15.6 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 into early 2021. 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 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 past the first quarter of 2021. 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.

Under General Instruction I.B.6 to Form S-3, or the Baby Shelf Rule, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates to the Company. We are currently limited by the Baby Shelf Rule as of the filing of this Quarterly Report on Form 10-Q, until such time as our public float exceeds $75 million. 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 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.

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 future clinical trials;
- manufacturing our products on a large scale and in a cost-effective manner;
- submitting applications for and obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of our product platform for treating pain; and

- establishing sales and marketing capabilities, as well as developing a manufacturing process and distribution network to support the commercialization of any approved products.

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

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 clinical trials for other treatment indications, even where we believe such data to be compelling. Our gammaCore therapy may fail to show the desired safety and efficacy traits in additional areas of indication in future clinical trials despite having progressed through preclinical and earlier stage clinical trials. Many companies in the pharmaceutical and medical device industries have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing clearance or approval of their products.

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

for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

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

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

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

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

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

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

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

Delays in the completion of any clinical trial of our gammaCore therapy will increase our costs, slow down our expansion into additional treatment indications and approval process, and delay or potentially jeopardize our ability to commence

product sales and generate future revenue. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory clearance or approval of our gammaCore therapy in additional treatment indications.

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

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

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

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

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

In addition, we may encounter delays if the FDA, or other regulators, conclude that our financial relationships with investigators results in a perceived or actual conflict of interest that may have affected the interpretation of a study, the

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

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

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

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

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

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

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

Because the COVID-19 pandemic affected, among other things, our access to prescribing physicians and their access to headache patients, on March 23, 2020 we suspended our earlier full-year revenue guidance until we could better understand the trajectory of our business, as well as announcing a reduction in our activities, and adjusting our cash runway expectations in response to the potential adverse impact caused by the COVID-19 pandemic.. Compared to our earlier expectations, we believe that our results for the quarter ended March 31, 2020 reflect a negative impact from, among other things, the global pandemic. Moreover, our expectations for the remainder of 2020 have also been adversely affected by both the uncertainty and potential negative impact of the global pandemic, which we believe may also have had an adverse effect on our access to debt and equity capital markets. Depending upon the duration and severity of the pandemic, the continuing effect on our results and outlook over the long term remains somewhat uncertain. In addition, the report of our auditors covering our consolidated financial statements at December 31, 2019 contained an explanatory paragraph stating that our recurring losses from operations and net capital deficiency raised substantial doubt about our ability to continue as a “going concern”. It was in this context that we believed we had a good faith basis that the economic uncertainty and negative impact on us and the economy as a whole due to the COVID-19 pandemic made an application for a loan pursuant to the PPP, under the Coronavirus Aid, Relief, and Economic Security Act, necessary for the support of our ongoing operations in the current economic environment.

On May 4, 2020, we entered into a PPP loan with Citibank, N.A. in an aggregate principal amount of approximately $1.4 million. On April 23, 2020, the Small Business Administration, or SBA, issued new guidance that questioned whether a public company with substantial market value and access to capital markets would qualify to participate in the PPP. Subsequently, on April 28, 2020 the Secretary of the Treasury and SBA announced that the government will review all PPP loans above $2 million in principal for which the borrower applies for forgiveness. On May 13, 2020, the SBA issued further guidance relating to the required necessity certification which provides a limited safe harbor for companies that received PPP loans having less than $2 million in principal to the effect that they will be deemed to have made the required certification concerning the necessity of the loan request in good faith. Nonetheless, should we be audited or reviewed by the U.S. Department of the Treasury as a result of filing an application for forgiveness or otherwise, such audit or review could result in the diversion of management's time and attention and legal and reputational costs. If we were to be audited and receive an adverse finding in such audit, we could be required to return the full amount of the PPP loan, which could reduce our liquidity, and potentially subject us to fines and penalties. Official guidance and interpretations of the requirements of the program have been limited and have been changing over time. Despite our good-faith belief that we properly satisfied all eligibility requirements for the PPP loan and the recently published, limited safe-harbor, there has been increasing scrutiny of public companies that received loans, and there can be no assurance that we will not become subject to regulatory or other scrutiny by the SBA, the Department of the Treasury or any other regulatory, administrative, legislative or governmental authority, including a request or requirement for re-payment of some or all of the loan.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties

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

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

Risk Related to our Dependence on Third Parties

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

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

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

acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

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

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

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

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

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

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

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

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

contracts or to bid on federal future contracts for a period of time lasting up to several years. Any of these contingencies could have a material adverse effect on our business, financial condition and results of operations.

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

In the United Kingdom, an 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 clinical trials and investigator - initiated trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Currently, we have an number of ongoing investigator-initiated trials, or IITs, including an IIT for nVNS stimulation in COVID-19 patients in Spain, and plans for additional IITs in the United States. Our reliance on third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. Furthermore, some of the sites for our investigator-initiated trials are outside the United States. The performance of these sites may be adversely affected by various issues, including less advanced medical infrastructure, lack of familiarity with conducting clinical trials in accordance with U.S. standards, insufficient training of personnel, communication difficulties or change in local regulations. We remain responsible for ensuring that clinical trials are conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, including our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory clearance or approval for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development, regulatory clearance and commercialization of our product candidates or may elect not to continue or renew development, regulatory clearance, or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that result from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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

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

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

expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

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

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

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

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

The manufacturing process requires lengthy lead times during which electronic components of our gammaCore therapy may become obsolete, and we may over- or under-estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third-party manufacturers exposes us to greater lead times increasing our risk of adverse financial impact of inventory obsolescence comparatively. In addition, as of March 31, 2020 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 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 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.

We recently submitted an Emergency Use Authorization, or EUA, application to the FDA to facilitate the study and clinical use of gammaCore Sapphire nVNS therapy for respiratory symptoms associated with COVID-19. However, there can be no assurance as to the timing of the review of an EUA submission nor whether the EUA ultimately will be granted.

On April 2, 2020, we announced the submission of an EUA application to the FDA to facilitate the study and clinical use of gammaCore Sapphire nVNS for respiratory symptoms associated with COVID-19. Although we believe that clinical data from certain pilot studies may suggest a possible benefit for patients with respiratory distress associated with COVID-19, it should be noted that preclinical and clinical data are often susceptible to varying interpretations and analyses, and that such data may not be adequate for the FDA to issue an EUA. It should also be noted that to date no randomized clinical trials have been performed utilizing gammaCore in patients with COVID-19. There can also be no assurance as to whether the EUA ultimately will be granted, and what impact, if any, an EUA for gammaCore Sapphire will have on us, our business, operations or financial condition.

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.

These compliance periods may be subject to delay due to temporary and generally applicable COVID-related relief from certain Nasdaq listing standards.

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

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

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

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

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

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

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

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

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

As described in *Item 1. Legal Proceedings*, we and certain of our present and past directors and officers have been named in putative securities class action lawsuits alleging violations of the Securities Act of 1933, or Securities Act, and the Exchange Act. We are generally required to indemnify our current and former directors and officers who are named as defendants in these types of lawsuits. We also have certain contractual indemnification obligations to the underwriters of our initial public offering, or IPO, regarding the securities class action lawsuits. While a certain amount of insurance coverage may be available for expenses or losses associated with these lawsuits, this coverage may not be sufficient. Although we plan to defend the lawsuits vigorously, there can be no assurances that favorable final outcomes will be obtained. Based on information currently available, we are unable to determine the reasonable probability of loss or a range of potential loss, and accordingly, we have not established an accrual for potential losses, if any, that could result from any unfavorable outcome, and there can be no assurance that these litigation matters, as well as any other lawsuits that might be brought by stockholders, will not result in substantial defense costs and/or judgments or settlements that could have a materially adverse impact on our financial position, results of operations and cash flows.

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

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

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

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

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

The trading market for our common stock is influenced by the research and reports that industry or securities analysts may publish about us or our business. If any of the analysts who cover us were to cease publishing research or reports about our business or were to issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our

stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

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

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

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

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

Additionally, the holders of approximately 14.6 million shares of our outstanding common stock, including shares issuable upon exercise of outstanding options and warrants, are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules. Sales of registered securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

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

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

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

Our ability to sell shares to Lincoln Park and obtain funds under the Purchase Agreement is limited by the terms and conditions in the Purchase Agreement, including restrictions on the amounts we may sell to Lincoln Park at any one time, and a limitation on our ability to sell shares to Lincoln Park to the extent that it would cause Lincoln Park to beneficially own more than 4.99% of our outstanding shares of common stock. Additionally, we will only be able to sell or issue to Lincoln Park a number of shares equal to 19.99% of the shares of common stock outstanding on the date of the Purchase Agreement unless we obtain shareholder approval to do so, or 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. We are seeking stockholder Approval at our upcoming annual meeting scheduled for June 12, 2020, but there can be no assurance that such Approval will be obtained. For these reasons, 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 March 15, 2020, 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 13.2 million shares of our voting stock which represents approximately 43.8% of our outstanding voting stock (treating all such vested options, warrants, restricted stock units and deferred stock units held by such persons as outstanding). These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

New legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results.

Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions may cause actual financial results to deviate from previous estimates.

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

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

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

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

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

Item 2. ***UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS***

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

The shares were registered under the Securities Act (File Nos. 333-225084 and 333-225804), on a registration statement on Form S-1, which was declared effective by the SEC, on June 21, 2018.

Through March 31, 2020, we used:

(i) approximately $8.0 million to fund activities related to commercialization of our gammaCore products which included hiring additional territory business managers as well as patient and professional promotional activities across multiple media channels,

(ii) approximately $4.3 million to fund expansion of our clinical program into additional indications in headache and rheumatology,

(iii) approximately $4.0 million for the build out of our specialty distribution channel for the launch of gammaCore Sapphire, and

(iv) approximately $48.3 million for working capital, including inventory, and other corporate purposes.

Item 3. ***DEFAULTS UPON SENIOR SECURITIES***

None.

Item 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

Item 5. ***OTHER INFORMATION***

(a)

Given the timing of the events, the following information is included in this Form 10-Q pursuant to Items 1.01 and 3.02 of Current Report on Form 8-K in lieu of filling a Current Report on Form 8-K.

On May 14, 2020, we entered into the SPA with our legal counsel, pursuant to which we agreed to issue 1,564,345 shares of common stock, par value $0.001 per share, to our counsel at a purchase price of $0.99 per share. The Purchase Price is equal to the "Minimum Price" as defined in the Listing Rules of the Nasdaq Stock Market LLC. Upon issuance to our counsel of the shares in the Private Placement, certain outstanding financial obligations owed to our counsel by the Company will be deemed paid and satisfied in full. The SPA contains customary representations, warranties, and covenants of the Company and our counsel, and the closing of the transaction is subject to customary closing conditions. In addition, our counsel was granted customary registration rights.

The representations, warranties, and covenants in the SPA were made solely for the purpose of the SPA and as of a specific date, are solely for the benefit of the parties to the SPA and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to security holders generally. Security holders should not rely on the representations, warranties, and covenants or descriptions thereof as characterizations of the actual state of facts or condition of the Company. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the SPA, which subsequent information may or may not be fully reflected in our public disclosures.

(b) Not applicable.

Item 6. *EXHIBITS*

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description
3.1	Certificate of Incorporation of electroCore, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2020 as filed with the Commission on May 15, 2020.)
3.2	Bylaws of electroCore, Inc. (Incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2020 as filed with the Commission on May 15, 2020.
10.1	Paycheck Protection Program Note between electroCore, Inc. and Citibank, N.A. (incorporated by reference to Exhibit 10.1 to the Current Report on 8-K as filed with the Commission on May 6, 2020.)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Company Name

Date: May 15, 2020

By: /s/ DANIEL S. GOLDBERGER

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

Date: May 15, 2020

By: /s/ BRIAN M. POSNER

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

EXHIBIT 31.1

CERTIFICATION

I, Daniel S. Goldberger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of electroCore, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2020

/s/ Daniel S. Goldberger

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

EXHIBIT 31.2

CERTIFICATION

I, Brian M. Posner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of electroCore, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2020

/s/ BRIAN M. POSNER

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

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of electroCore, Inc, (the "Company") for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel S. Goldberger, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to the best of my knowledge:

1. The Report complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2020

/s/ Daniel S. Goldberger
Daniel S. Goldberger
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of electroCore, Inc. (the "Company") for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Brian M. Posner, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2020

/s/ BRIAN M. POSNER
Brian M. Posner
Chief Financial Officer
(Principal Financial and Accounting Officer)