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 September 30, 2019

☐ **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 November 8, 2019, the registrant had 29,514,434 shares of common stock outstanding.

PART I. FINANCIAL INFORMATION

		Page
	Cautionary Note Regarding Forward-Looking Statements	3
Item 1.	Financial Statements	
	Consolidated Balance Sheets as of September 30, 2019 (unaudited) and December 31, 2018	4
	Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2019 and 2018 (Unaudited)	5
	Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2019 and 2018 (Unaudited)	6
	Consolidated Statements of Changes in Convertible Preferred Units, Members' (Deficit) and Stockholders' Equity for the Three and Nine Months Ended September 30, 2019 and 2018 (Unaudited)	7
	Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2019 and 2018 (Unaudited)	9
	Notes to Consolidated Financial Statements (Unaudited)	10
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	34
Item 4.	Controls and Procedures	34
	PART II. OTHER INFORMATION	
Item 1.	Legal Proceedings	36
Item 1A.	Risk Factors	36
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	82
Item 3.	Defaults Upon Senior Securities	82
Item 4.	Mine Safety Disclosures	82
Item 5.	Other Information	82
Item 6.	Exhibits	83
	Signatures	84

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" following the date of the Corporate Conversion (June 21, 2018) refer to electroCore, Inc. a Delaware corporation, and its subsidiaries and affiliate; references to the "Company," "electroCore," "we," "us" and "our" prior to the date of the Corporate Conversion refer to ElectroCore, LLC, a Delaware limited liability company, and its subsidiaries and affiliate; and references to the "Corporate Conversion" or "corporate conversion" refer to all of the transactions related to the statutory conversion of ElectroCore, LLC from a Delaware limited liability company to a Delaware corporation and the change of its name to electroCore, Inc., effected on June 21, 2018.

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 (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those included in our Annual Report on Form 10-K dated December 31, 2018, filed with the SEC described under "Risk Factors" and in "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

	September 30, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 6,548,506	$ 7,600,284
Marketable securities	26,939,593	60,963,087
Accounts receivable, net	753,377	267,599
Inventories, net	3,111,271	1,949,402
Prepaid expenses and other current assets	1,597,250	1,918,164
Total current assets	38,949,997	72,698,536
Inventories, noncurrent	2,010,000	—
Property and equipment, net	371,408	380,904
Operating lease right of use assets	1,552,537	—
Other assets	1,206,509	424,896
Total assets	$ 44,090,451	$ 73,504,336
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,630,357	$ 2,698,902
Accrued expenses	3,717,270	4,374,101
Note payable	461,341	—
Current portion of operating lease liabilities	436,904	—
Total current liabilities	10,245,872	7,073,003
Noncurrent liabilities:		
Deferred rent	—	245,632
Operating lease liabilities	1,550,065	—
Total liabilities	11,795,937	7,318,635
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, par value $0.001 per share; 10,000,000 shares authorized at September 30, 2019 and December 31, 2018; 0 shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common Stock, par value $0.001 per share; 500,000,000 shares authorized at September 30, 2019 and December 31, 2018; 29,468,966 issued and outstanding at September 30, 2019 and 29,450,035 shares issued and outstanding at December 31, 2018	29,468	29,450
Additional paid-in capital	106,498,093	103,791,013
Accumulated deficit	(74,981,008)	(38,331,215)
Accumulated other comprehensive income	112,351	60,843
Total stockholders' equity	31,658,904	65,550,091
Noncontrolling interest	635,610	635,610
Total equity	32,294,514	66,185,701
Total liabilities and equity	$ 44,090,451	$ 73,504,336

See accompanying notes to unaudited consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Operations
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net sales	$ 682,993	$ 150,972	$ 1,715,337	$ 625,385
Cost of goods sold	353,939	97,067	766,173	386,502
Gross profit	329,054	53,905	949,164	238,883
Operating expenses:				
Research and development	2,274,855	2,333,255	8,279,432	9,006,659
Selling, general and administrative	8,143,356	11,272,531	28,155,604	30,104,551
Restructuring and other severance related charges	804,643	—	1,997,292	—
Total operating expenses	11,222,854	13,605,786	38,432,328	39,111,210
Loss from operations	(10,893,800)	(13,551,881)	(37,483,164)	(38,872,327)
Other income/(expense)				
Change in fair value of warrant liability	—	—	—	(1,870,923)
Interest and other income, net	206,057	355,228	850,062	579,838
Other expense	—	(4,856)	(16,692)	(263,728)
Total other income/(expense)	206,057	350,372	833,370	(1,554,813)
Loss before income taxes	(10,687,743)	(13,201,509)	(36,649,794)	(40,427,140)
Provision for income taxes	—	2,431	—	2,431
Net loss from operations	(10,687,743)	(13,203,940)	(36,649,794)	(40,429,571)
Less: Net income attributable to noncontrolling interest	—	—	—	55,005
Total net loss attributable to Electrocore LLC and electroCore, Inc., subsidiaries and affiliate	$ (10,687,743)	$ (13,203,940)	$ (36,649,794)	$ (40,484,576)
Net loss attributable to Electrocore, LLC subsidiaries and affiliate	$ —	$ —	$ —	$ (21,118,337)
Net loss attributable to electroCore, Inc., subsidiaries and affiliate	$ (10,687,743)	$ (13,203,940)	$ (36,649,794)	$ (19,366,239)
Net loss per share of common stock - Basic and Diluted (see Note 14)	$ (0.36)	$ (0.45)	$ (1.25)	$ (0.66)
Weighted average common shares outstanding - Basic and Diluted (see Note 14)	29,352,026	29,261,942	29,339,384	29,261,942

See accompanying notes to unaudited consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Net loss from operations	$ (10,687,743)	$ (13,203,940)	$ (36,649,794)	$ (40,429,571)
Other comprehensive income/(loss):				
Foreign currency translation adjustment	17,674	27,094	5,935	(25,553)
Amount reclassified from accumulated OCI	_	2	_	11,026
Unrealized (loss)/gains on securities, net of taxes as applicable	(10,781)	(38,383)	45,628	(35,232)
Other comprehensive income/(loss)	6,893	(11,287)	51,563	(49,759)
Comprehensive loss	(10,680,850)	(13,215,227)	(36,598,231)	(40,479,330)
Less: Net comprehensive income attributable to noncontrolling interest	—	_	—	5,085
Comprehensive loss attributable to Electrocore, LLC and electroCore, Inc., subsidiaries and affiliate	$ (10,680,850)	$ (13,215,227)	$ (36,598,231)	$ (40,474,245)
Comprehensive loss attributable to Electrocore, LLC subsidiaries and affiliate	$ —	$ —	$ —	$ (21,118,056)
Comprehensive loss attributable to electroCore, Inc., subsidiaries and affiliate	$ (10,680,850)	$ (13,215,227)	$ (36,598,231)	$ (19,356,189)

See accompanying notes to unaudited consolidated financial statements.

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Changes in Convertible Preferred Units, Members' (Deficit) and Stockholders' Equity
(Unaudited)

	Series A Preferred Units		Series B Preferred Units		Common Units		Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	(Deficit)/Equity attributable to Electrocore LLC and electroCore, Inc., subsidiaries and affiliate	Noncontrolling interest	Total equity/ (deficit)
	Units	Amount	Units	Amount	Units	Amount	Shares	Amount						
Balances as of December 31, 2017	70,918,506	$ 53,518,463	105,186,020	$ 68,755,544	218,982,140	$ 40,180,619	—	$ —	$ 22,596,485	$ (152,928,928)	$ 80,213	$ (90,071,611)	$ 604,055	$ (89,467,556)
Net loss attributable to Electrocore, LLC subsidiaries and affiliate	—	—	—	—	—	—	—	—	—	(9,498,540)	—	(9,498,540)	55,005	(9,443,535)
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	(139,261)	(139,261)	—	(139,261)
Noncontrolling interest distributions	—	—	—	—	—	—	—	—	—	—	—	—	(49,920)	(49,920)
Stock and Unit-based compensation	—	—	—	—	—	—	—	—	267,145	—	—	267,145	—	267,145
Balances as of March 31, 2018	70,918,506	$ 53,518,463	105,186,020	$ 68,755,544	218,982,140	$ 40,180,619	—	$ —	$ 22,863,630	$ (162,427,468)	$ (59,048)	$ (99,442,267)	$ 609,140	$ (98,833,127)
Net loss attributable to electroCore, LLC subsidiaries and affiliate	—	—	—	—	—	—	—	—	—	(11,619,797)	(5,085)	(11,624,882)	5,085	(11,619,797)
Reclass of accumulated deficit to APIC	—	—	—	—	—	—	—	—	(174,047,265)	174,047,265	—	—	—	—
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	105,873	105,873	(5,085)	100,788
Conversion of Series A preferred units to common stock	(70,918,506)	(53,518,463)	—	—	—	—	3,939,917	3,940	53,514,523	—	—	53,518,463	—	53,518,463
Conversion of Series B preferred units to common stock	—	—	(105,186,020)	(68,755,544)	—	—	5,843,668	5,844	68,749,700	—	—	68,755,544	—	68,755,544
Conversion of members common units to common stock	—	—	—	—	(218,982,140)	(40,180,619)	12,099,280	12,099	40,168,520	—	—	—	—	—
Stock dividend issued to Series A preferred holders	—	—	—	—	—	—	241,939	242	3,628,850	(3,629,092)	—	—	—	—
Common stock issued related to initial public offering	—	—	—	—	—	—	5,980,000	5,980	89,692,675	—	—	89,698,655	—	89,698,655
Issuance costs related to initial public offering	—	—	—	—	—	—	—	—	(12,012,086)	—	—	(12,012,086)	—	(12,012,086)
Reclass of warrant liability to equity	—	—	—	—	—	—	—	—	4,110,467	—	—	4,110,467	—	4,110,467
Noncontrolling interest distributions	—	—	—	—	—	—	—	—	—	—	—	—	26,469	26,469
Stock issued upon conversion of profit interests	—	—	—	—	—	—	1,345,230	1,345	—	—	—	1,345	—	1,345
Stock and Unit-based compensation	—	—	—	—	—	—	—	—	5,364,448	—	—	5,364,448	—	5,364,448
Net loss attributable to electroCore, Inc., subsidiaries and affiliate	—	—	—	—	—	—	—	—	—	(6,162,299)	—	(6,162,299)	—	(6,162,299)
Balances as of June 30, 2018	—	$ —	—	$ —	—	$ —	29,450,034	$ 29,450	$ 102,033,462	$ (9,791,391)	$ 41,740	$ 92,313,261	$ 635,609	$ 92,948,870
Net loss attributable to electroCore, Inc., subsidiaries and affiliate	—	—	—	—	—	—	—	—	—	(13,203,940)	—	(13,203,940)	—	(13,203,940)
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	(11,286)	(11,286)	—	(11,286)
Noncontrolling interest distributions	—	—	—	—	—	—	—	—	—	—	—	—	1	1
Stock based compensation (net of forfeitures)	—	—	—	—	—	—	—	—	661,170	—	—	661,170	—	661,170
Balances as of September 30, 2018	$ —	$ —	$ —	$ —	$ —	$ —	29,450,034	$ 29,450	$ 102,694,632	$ (22,995,331)	$ 30,454	$ 79,759,205	$ 635,610	$ 80,394,815

See accompanying notes to unaudited consolidated financial statements

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Changes in Convertible Preferred Units, Members' (Deficit) and Stockholders' Equity
(Unaudited)

	Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	(Deficit)/Equity attributable to Electrocore LLC and electroCore, Inc., subsidiaries and affiliate	Noncontrolling interest	Total equity/ (deficit)
	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
Stock issuance	183,205	183	(183)	—	—	—	—	—
Stock based compensation (net of forfeitures)	—	—	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
Net loss	—	—	—	(12,100,520)	—	(12,100,520)	—	(12,100,520)
Other comprehensive income	—	—	—	—	(39,098)	(39,098)	—	(39,098)
Stock cancellations	(51,549)	(52)	52	—	—	—	—	—
Stock based compensation (net of forfeitures)	—	—	726,799	—	—	726,799	—	726,799
Balances as of June 30, 2019	29,581,691	$ 29,581	$ 105,278,405	$ (64,293,265)	$ 105,458	$ 41,120,179	$ 635,610	$ 41,755,789
Net loss	—	—	—	(10,687,743)	—	(10,687,743)	—	(10,687,743)
Other comprehensive income	—	—	—	—	6,893	6,893	—	6,893
Stock cancellations	(140,927)	(141)	141	—	—	—	—	—
Stock issuance under the employee stock purchase plan	28,202	28	(28)	—	—	—	—	
Stock based compensation (net of forfeitures)	—	—	1,219,575	—	—	1,219,575	—	1,219,575
Balances as of September 30, 2019	29,468,966	$ 29,468	$ 106,498,093	$ (74,981,008)	$ 112,351	$ 31,658,904	$ 635,610	$ 32,294,514

See accompanying notes to unaudited consolidated financial statements

ELECTROCORE, INC., SUBSIDIARIES AND AFFILIATE

Consolidated Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss from operations	$ (36,649,794)	$ (40,429,571)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrants and embedded derivative	—	1,870,923
Stock/unit-based compensation	2,690,406	6,458,115
Depreciation and amortization	152,255	41,727
Amortization of marketable securities discount	(480,840)	(240,620)
Cloud computing arrangement implementation costs	(1,114,568)	—
Net noncash lease expense	411,142	—
Noncash portion of litigation settlement	16,692	—
Other	(157,759)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(485,778)	(124,104)
Inventories	(3,171,868)	(796,445)
Prepaid expenses and other current assets	274,199	(2,555,468)
Accounts payable	3,219,105	887,399
Accrued expense and other current liabilities	(656,734)	—
Deferred rent	—	(44,389)
Net cash used in operating activities	(35,953,542)	(34,932,433)
Cash flows from investing activities:		
Purchase of marketable securities	(35,216,037)	(56,589,240)
Proceeds from maturities of marketable securities	69,766,000	26,509,684
Purchases of property and equipment	(72,241)	(278,921)
Net cash provided by (used in) investing activities	34,477,722	(30,358,477)
Cash flows from financing activities:		
Proceeds from note issued	807,347	—
Repayments of note issued	(346,006)	—
Sale of common stock, net of related expenses	—	78,379,457
Net cash provided by financing activities	461,341	78,379,457
Effect of changes in exchange rates on cash and cash equivalents	(37,299)	(49,004)
Net (decrease) increase in cash and cash equivalents	(1,051,778)	13,039,543
Cash and cash equivalents – beginning of period	7,600,284	13,224,194
Cash and cash equivalents – end of period	$ 6,548,506	$ 26,263,737
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,457	$ —
Supplemental schedule of noncash activity:		
Prepaid lease payments included in right of use assets	$ 42,857	$ —
Series A preferred nits converted to common stock	$ —	$ 53,518,463
Series B units converted to common stock	$ —	$ 68,755,544
Members common units converted to common stock	$ —	$ 40,180,619
Reclass of warrant liability to additional paid in capital	$ —	$ 4,110,467
Reclass of deferred financing costs to additional paid in capital	$ —	$ 856,985
Stock dividend distribution in connection with IPO	$ —	$ 3,629,092

See accompanying notes to unaudited consolidated financial statements.

Note 1. Corporate Organization and Company Overview

Company Overview

electroCore, Inc. is a commercial-stage bioelectronic medicine 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 wholly owned subsidiaries that include: electroCore Bermuda, Ltd. (see Note 22), electroCore Germany GmbH, and electroCore UK Ltd. In addition, an inactive affiliate, electroCore (Aust) Pty Limited, is subject to electroCore’s control on basis other than voting interests and is a variable interest entity (“VIE”), for which electroCore is the primary beneficiary.

Corporate Conversion and Initial Public Offering

Effective June 21, 2018, the Company converted into a Delaware corporation pursuant to a statutory conversion and changed its name to electroCore, Inc. Previously, the Company operated as a Delaware limited liability company under the name Electrocore, LLC. As a result of the corporate conversion, the holders of the different series of units of Electrocore, LLC, or Units, became holders of common stock and options to purchase common stock of electroCore, Inc. Warrants to purchase Units were converted to warrants to purchase common stock of electroCore, Inc. The number of shares of common stock, options to purchase common stock, and warrants to purchase common stock that holders of Units and warrants to purchase Units were entitled to receive in the corporate conversion was determined in accordance with a plan of conversion that was based upon the terms of the Company’s Third Amended and Restated Limited Liability Company Agreement, dated November 21, 2017 (the “Operating Agreement”), and varied depending on which class and series of Units a holder owned, and the terms of the applicable warrants. See Note 15 - Corporate Conversion and Equity.

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

Note 2. Basis of Presentation

The accompanying unaudited consolidated financial statements were prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”) and with Article 10 of Regulation S-X for interim financial reporting. In compliance with those rules, certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and related notes for the fiscal year ended December 31, 2018 included in the Annual Report on Form 10-K filed with the SEC. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair statement of the results of interim periods have been included. The results of operations and cash flows reported in these consolidated financial statements should not be regarded as necessarily indicative of results that may be expected for the entire fiscal year.

In previous quarters of 2019, certain severance related costs were classified as selling, general and administrative expense. These amounts have been reclassified as restructuring and other severance related costs for the nine months ended September 30, 2019. In addition, in previous quarters of 2019, certain stock related items have been reclassed from stock based compensation into separate lines on the consolidated statements of stockholders’ equity.

Note 3. Summary of Significant Accounting Policies

(a) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of electroCore and its wholly owned subsidiaries. In addition, an inactive affiliate, electroCore (Aust) Pty Limited, a variable interest entity (“VIE”) for which electroCore is the

primary beneficiary, is also consolidated with the non-controlled equity presented as non-controlling interest. All intercompany balances and transactions have been eliminated in consolidation.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. 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 and sales returns; valuation of inventory, stock compensation, and contingencies.

(c) Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued an accounting standard update ("ASU") that provided the principles for the recognition, measurement, presentation and disclosure of leases. The guidance amended the existing accounting standards, including the requirement that lessees recognize right-of-use assets and lease liabilities for leases with terms greater than 12 months in their consolidated balance sheets. Additional guidance and targeted improvements to the February 2016 ASU were made through the issuance of supplementary ASUs in July 2018, December 2018 and March 2019. The Company refers to all three ASUs collectively as the "new lease standard."

The Company adopted the new lease standard on January 1, 2019 and applied it to leases that were in place on the effective date. Results for reporting periods beginning January 1, 2019 are presented under the new lease standard.

The new lease accounting guidance permits companies to utilize certain practical expedients in their implementation of the new standard. The Company elected this package of practical expedients and was therefore not required to reassess the following upon adoption: (i) whether an expired or existing contract met the definition of a lease; (ii) the lease classification at January 1, 2019 for existing leases; and (iii) whether leasing costs previously capitalized as initial direct costs would continue to be amortized. This allowed the Company to continue to account for its existing office space leases as operating leases. Upon adoption, the Company did not have an adjustment to the opening balance of retained earnings due to the election of these practical expedients.

At January 1, 2019, the Company recognized Lease Right-of-Use ("ROU") Assets and Lease Liabilities, principally for its office space leases, in which it is the lessee, on the Consolidated Balance Sheets. (See Note 10. Leases)

(d) Recent Accounting Pronouncements Not Yet Adopted

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

Note 4. Risks and Uncertainties

The Company's cash requirements for 2019 and beyond include expenses related to the commercialization of its products, as well as the continuing development and clinical evaluation of its products and therapies. As of September 30, 2019 the Company had working capital (current assets less current liabilities) of $28.7 million.

The Company's expected cash requirements for 2019 and beyond are based on the commercial success of its products and the continual development and clinical evaluation of its products and therapies. Based on the Company's available cash resources and cash flow projections, it believes it has sufficient funds to continue operations for at least the next 12 months. If these projections are not achieved, the Company will have to further reduce non-personnel related discretionary spending to continue its operations for at least the next 12 months. Until the Company can generate significant cash from its operations, the Company expects to continue to fund its operations with its available financial resources. To the extent additional funds are necessary to meet long-term liquidity needs as the Company continues to execute its business strategy, the Company anticipates that it will be obtained through the incurrence of indebtedness, equity financings or a combination of these potential sources of funds, although the Company can provide no assurance that these sources of funding will be available on reasonable terms.

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

The Company earns a significant amount of its revenue from one specialty pharmaceutical distributor in the United States. At September 30, 2019 and December 31, 2018, the accounts receivable, net related to this distributor was $213,850 and $195,730 respectively.

Note 5. Revenue Recognition

Performance Obligations

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

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

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

From February 2018 to mid-July 2018 vouchers were used by physicians to provide new patients with free therapy (i.e., one gammaCore device) by delivering non-voucher units for the free therapy. The transaction price of the non-voucher units redeemed and estimated to be redeemed was recognized as contra-revenue. The costs to produce these units, in addition to any processing fees, are included as promotional expenses in selling, general and administrative expense. After mid-July 2018, the Company modified its voucher program to provide its distributor with gammaCore and gammaCore Sapphire promotional units at no charge ("voucher units"). The voucher units have a distinct product item number to be used for the voucher program. The costs to produce these voucher units given to patients under the voucher program are recognized in promotional expense.

In October 2018, the Company launched its *Partners for Coverage* program that allows eligible commercial insurance patients uninterrupted access to gammaCore for up to two months while insurance coverage is being pursued. In February 2019, this program was modified to provide therapy to patients for up to 12 months while insurance coverage is being pursued.

In addition, reimbursement for co-payments made by patients under the co-payment assistance program is considered variable consideration. Beginning in February 2019, eligible patients could receive a reduction of up to $300 from the cost of co-payments the first month of therapy and a reduction of up to $250 from the cost of each refill for a maximum of 12 months. For three and nine months ended September 30, 2019, net product sales reflect a reduction of $18,567 and $56,959, respectively, for the reduction from the cost of therapy under the co-payment assistance program. For the three and nine months ended September 30, 2018, net product sales reflect a reduction of $14,615 and $54,340 respectively, from the cost of therapy under the co-payment assistance program.

In accordance with Company policy, damaged or defective products are replaced at no charge under the Company's standard warranty. A cash refund is allowed under specific circumstances for undamaged and non-defective returned products. As of September 30, 2019, and December 31, 2018 the allowance for returns was $130,000 and $0, respectively.

Contract Balances

The Company generally invoices the customer and recognizes revenue once its performance obligations are satisfied, at which point payment is unconditional. Accordingly, under ASC 606, the contracts with customers do not give rise to contract assets or liabilities.

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

Disaggregation of Net Sales

The following table provides additional information pertaining to net sales disaggregated by geographic market for the three and nine months ended September 30, 2019 and 2018:

	For the three months ended September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Geographic Market				
United States	$ 491,722	$ 8,905	$ 1,211,318	$ 338,753
United Kingdom	169,526	97,278	415,313	213,041
Germany	18,113	42,884	79,452	60,343
Other	3,632	1,905	9,254	13,248
Total Net Sales	$ 682,993	$ 150,972	$ 1,715,337	$ 625,385

Note 6. Cash, Cash Equivalents and Marketable Securities

The following tables summarizes the Company's cash, cash equivalents and marketable securities as of September 30, 2019 and December 31, 2018.

As of September 30, 2019

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 6,548,506	$ —	$ —	$ 6,548,506
Commercial Paper	$ 1,992,987	$ 1,273	$ —	$ 1,994,260
U.S. Treasury Bonds	24,943,908	3,141	(1,716)	24,945,333
Total marketable securities	$ 26,936,895	$ 4,414	$ (1,716)	$ 26,939,593
Total cash, cash equivalents, and marketable securities	$ 33,485,401	$ 4,414	$ (1,716)	$ 33,488,099

As of December 31, 2018

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 7,600,284	$ —	$ —	$ 7,600,284
Corporate Debt Securities	$ 18,961,145	$ —	$ (25,888)	$ 18,935,257
Commercial Paper	6,970,867	—	(4,927)	6,965,940
U.S. Treasury Bonds	35,074,005	—	(12,115)	35,061,890
Total marketable securities	$ 61,006,017	$ —	$ (42,930)	$ 60,963,087
Total cash, cash equivalents, and marketable securities	$ 68,606,301	$ —	$ (42,930)	$ 68,563,371

The Company's commercial paper and U.S. treasury bonds all mature within one year.

Note 7. Fair Value Measurements

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

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

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

		Fair Value Hierarchy		
September 30, 2019	**Total**	**(Level 1)**	**(Level 2)**	**(Level 3)**
Assets				
Cash and cash equivalents	$ 6,548,506	$ 6,548,506	$ —	$ —
Marketable Securities:				
Commercial Paper	1,994,260	1,994,260	—	—
U.S. Treasury Bonds	24,945,333	24,945,333	—	—
Total	$ 33,488,099	$ 33,488,099	$ —	$ —
December 31, 2018				
Assets				
Cash and cash equivalents	$ 7,600,284	$ 7,600,284	$ —	$ —
Marketable Securities:				
Corporate Debt Securities	18,935,257	18,935,257	—	—
Commercial Paper	6,965,940	6,965,940	—	—
U.S. Government Sponsored Agencies	35,061,890	35,061,890	—	—
Total	$ 68,563,371	$ 68,563,371	$ —	$ —

The carrying amount of the Company's receivables and payables approximate their fair values due to their short maturities, and therefore their fair value information is not included in the above table.

Note 8. Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in first-out basis.

	September 30, 2019	December 31, 2018
Raw materials	$ 1,330,419	$ 821,704
Work in process	3,569,131	951,695
Finished goods	221,721	176,003
Total inventory	5,121,271	1,949,402
Less: noncurrent	2,010,000	—
Total - current	$ 3,111,271	$ 1,949,402

Note 9. Property and Equipment – Net

Property and equipment, net, as of September 30, 2019 and December 31, 2018 consisted of the following:

	September 30, 2019	December 31, 2018
Machinery and equipment	$ 393,154	$ 424,146
Furniture and fixture	309,311	286,268
Computer equipment	20,783	20,783
Leasehold Improvements	8,880	—
Property and equipment - gross	732,128	731,197
Less accumulated depreciation and amortization	(360,720)	(350,293)
Property and equipment - net	$ 371,408	$ 380,904

During the nine months ended September 30, 2019, $70,639 of fully depreciated lab and production equipment and office furniture were written off. During the nine months ended September 30, 2018, $27,204 of fully depreciated assets held by the Company's Bermuda and Australian subsidiaries were written off.

Property and Equipment depreciation and amortization expense for the three and nine months ended September 30, 2019 was $27,366 and $81,066, respectively. Depreciation and amortization expense for the three and nine months ended September 30, 2018 was $20,663 and $41,727, respectively

Note 10. Leases

The Company implemented FASB ASU 2016-02, Leases (Topic 842), which required lessees to recognize most leases on the balance sheet effective January 1, 2019. The Company recognized $3.9 million of right of use assets for leases for office, manufacturing and warehouse space and office equipment. The Company also recognized $4.2 million for lease liabilities. The Company has elected not to recognize right of use assets and lease liabilities for short term leases, i.e., leases with a noncancelable period of 12 months or less.

The Company's leases have remaining lease terms of approximately three to five years, some of which include options to extend the leases for up to an additional five years. For the leases for the office space in Basking Ridge New Jersey and the manufacturing and warehouse space in Rockaway New Jersey, the Company recognized the options to renew the leases as part of the right of use asset and the lease liability as the Company deemed that the renewal options were reasonably certain to be exercised. However, due to the Company's decision to implement a comprehensive redeployment and cost reduction plan implemented in June 2019, the Company determined the renewal option for the office space at the Basking Ridge location is no longer reasonably certain to be exercised. The Company remeasured the Basking Ridge right of use asset and the lease liability beginning June 1, 2019 utilizing the newly expected lease term.

The incremental borrowing rate used to determine the net present value of the leases at inception was 9.75%. This is the incremental borrowing rate that represents the rate of interest that the Company would expect to pay to borrow an amount equal to the lease payments under similar terms. As the Company does not borrow on a collateralized basis, the non-collateralized borrowing rate is used as an input in deriving the incremental borrowing rate. Following the comprehensive redeployment and cost reduction plan announcement and as required in the lease remeasurement process under Topic 842, the incremental borrowing rate was reassessed and increased to 13.75% at the time of remeasurement. The remeasurement updated the net present value of all operating leases from inception using the new discount rate at June 1, 2019.

For the three months ended September 30, 2019 and 2018, the Company recognized lease expense of $186,037 and $124,068, respectively. For the nine months ended September 30, 2019 and 2018, the Company recognized lease expense of $599,322 and $371,227, respectively. These payments do not include non-lease components as the Company elected not to include those payments 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

	September 30, 2019
Operating leases:	
Operating lease right of use assets	$ 1,552,537
Operating lease liabilities:	
Current portion of operating lease liabilities	436,904
Noncurrent operating lease liabilities	1,550,065
Total operating lease liabilities	$ 1,986,969
Weighted average remaining lease term (in years)	5.9
Weighted average discount rate	13.75%

Supplemental Statement of Cash Flows Information for Operating Leases

	Nine months ended September 30, 2019
Noncash lease expense	232,270
Change in operating lease liabilities	178,872

Future minimum lease payments under non-cancellable operating leases as of September 30, 2019:

Remainder of 2019	$ 145,103
2020	712,076
2021	690,358
2022	337,254
2023	142,892
2024 and thereafter	822,304
Total future minimum lease payments	2,849,987
Less: Amounts representing interest	(863,018)
Total	$ 1,986,969

Total lease expense, in accordance with the superseded lease standard was $496,055 for 2018. Future minimum lease payments under non-cancellable operating leases as of December 31, 2018:

Year ended December 31, 2019	$ 576,743
2020	714,616
2021	692,893
2022	737,324
2023 and thereafter	3,696,796
Total	$ 6,418,372

Note 11. Other Assets

In 2018, the Company entered into a contract to obtain a cloud computing arrangement (“CCA”). In accordance with ASU 2018-15, the implementation costs incurred in the CCA are deferred and recognized as other assets and are amortized to expense over the noncancelable term of the arrangement. The Company capitalized $826,818 in CCA costs for the six months ended June 30, 2019 and $395,504 in the last quarter of 2018. 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, or $23,506 a month over 52 months. Amortization costs for the three and nine months ended September 30, 2019 was $70,519.

Note 12. Accrued Expenses

Accrued expenses as of September 30, 2019 and December 31, 2018 consisted of the following:

	September 30, 2019	December 31, 2018
Accrued professional fees	1,049,189	1,273,249
Accrued bonuses	785,878	2,152,264
Restructuring and severance accrual	1,155,328	—
Other accrued expenses	726,875	948,588
	$ 3,717,270	$ 4,374,101

Note 13. Note Payable

Finance and Security Agreement

On July 1, 2019, the Company entered into a Commercial Insurance Premium Finance and Security Agreement ("the Agreement"). The Agreement provides 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 are secured by the Company's rights under such policies. At September 30, 2019, the remaining balance is $461,341 and during the three and nine months ended September 30, 2019, the Company recognized $3,457 in interest expense, respectively.

Note 14. Net Loss Per Share

Stock options have not been included in the diluted earnings per share calculation as they have been determined to be anti-dilutive under the treasury stock method. As described in Note 15, Corporate Conversion and Equity, on June 21, 2018, electroCore, Inc. completed a Corporate Conversion as well as its IPO to, among other things, provide for a single class of common stock of electroCore Inc., in exchange for the previous Convertible Preferred Units and Common Units of the Company. This conversion changed the relative ownership of electroCore, Inc. such that retroactive application of the conversion to periods prior to the IPO for the purposes of calculating loss per share would not be meaningful.

Prior to the Corporate Conversion, the Company's ownership structure included several different types of LLC interests including preferred stock, common units and Profits Interests (see Note 15, Corporate Conversion and Equity). The Company analyzed the calculation of earnings per unit for periods prior to the Corporate Conversion and determined that it resulted in values that would not be meaningful to the users of these consolidated financial statements. Therefore, earnings per share information has not been presented for periods prior to the Corporate Conversion on June 21, 2018

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

	For the three months ended September 30, 2019	For the three months ended September 30, 2018	For the nine months ended September 30, 2019	For the period from June 21 to September 30, 2018
Numerator – Basic and Diluted				
Net loss attributable to electroCore, Inc. subsidiaries and affiliate	$ (10,687,743)	$ (13,203,940)	$ (36,649,794)	$ (19,366,239)
Denominator – Basic and Diluted				
Weighted average shares of common stock outstanding	29,352,026	29,261,942	29,339,384	29,261,942
Net loss per common share, Basic and Diluted	$ (0.36)	$ (0.45)	$ (1.25)	$ (0.66)

Note 15. Corporate Conversion and Equity

On June 21, 2018, the Company completed the Corporate Conversion. Pursuant to the certificate of incorporation effected in connection with the Corporate Conversion, the Company's authorized capital stock consists of 500 million shares of common stock, par value $0.001 per share and 10 million shares of preferred stock, par value $0.001 per share. As a result of this conversion and related IPO, 29,450,034 shares of common stock and zero shares of preferred stock were issued. Prior to the Corporate Conversion of the Company, the Operating Agreement permitted the issuance of four classes of Units - Series A Preferred Units, Series B Preferred Units, Series B-1 Preferred Units and Common Units. Except as otherwise provided in the Operating Agreement, each member was entitled to one vote for each Unit held and the Units of all classes and series voted together as a single class on all matters (on an as converted to Common Unit basis).

Upon the Corporate Conversion, all Units were converted into an aggregate of 23,470,034 shares of common stock and options to purchase 2,141,751 shares of common stock as follows:

- holders of common units, or Common Units, other than Common Units that were originally issued as "profits interests" (as such term is used for purposes of the Internal Revenue Code), or Profits Interests, received an aggregate of 12,099,280 shares of common stock;
- holders of Series A Preferred Units received an aggregate of 4,181,856 shares of common stock, which included 241,939 shares of common stock as payment in full of the approximately $3.6 million accrued and unpaid preferred return that was payable in respect of the Series A Preferred Units;
- holders of Series B Preferred Units received an aggregate of 5,843,668 shares of common stock;
- holders of Profits Interests received an aggregate of 1,345,231 shares of common stock; and
- holders of Profits Interests who were employees or consultants at the time of the corporate conversion received options to purchase an aggregate of 2,141,751 shares of common stock, with an exercise price of $15.00 which was equal to the IPO price.

Additionally, upon the conversion, the accumulated deficit of Electrocore LLC, subsidiaries and affiliates was reclassed to additional paid in capital in accordance with SEC Staff Accounting Bulletin Topic 4B.

Series A Preferred Units

The Series A Preferred Units were entitled to a preference on distributions, ahead of the Common Units but behind Series B Preferred Units, in the amount of $54,923,430 plus the Series A Preferred Return (as described below), as of June 20, 2018.

The Series A Preferred Units were entitled to a return in an annual non-compounded amount with respect to each outstanding Series A Preferred Unit equal to the product of the Series A Preferred Return Percentage and the Series A Unreturned Capital Value for each Unit, which accrued to the extent not paid. The Series A Preferred Return Percentage was 4% and could be reduced to 2% if certain requirements were met as outlined in the amended and restated Operating Agreement. Upon an IPO, the payment of the Series A Preferred Return was at the sole discretion of the Board of Managers. As of June 20, 2018, the Series A Preferred Return payable, following the 2017 amendments to the Operating Agreement, upon a public offering of the Company's common stock was fixed at $3,629,092. This amount was paid with the issuance of 241,939 shares of common stock upon the IPO.

The Series A Preferred Units were converted into common stock mandatorily immediately prior to the IPO as outlined in the amended and restated Operating Agreement, and then subject to a 1:18 stock conversion.

As of June 20, 2018, there were no outstanding warrants to purchase Series A Preferred Units, except for warrants to purchase in the aggregate 221,766 Series A Preferred Units issued in connection with the December 2015 term loan (which was repaid and/or converted into equity in 2016) and as compensation to one of the financial advisors. In connection with the IPO, these outstanding Series A warrants by their terms converted into warrants to purchase in the aggregate 12,321 shares of common stock at an exercise price of $15.30 per share.

Series B Preferred Units

In 2017, the Company entered into a Series B Preferred Unit Purchase Agreement with multiple investors, including Core Ventures II, LLC and Merck Global Health Innovation Fund. Under the terms of the Purchase Agreement, as amended, through December 31, 2017, the Company received cash proceeds of $46,911,300 and converted $26,718,910 of outstanding

promissory notes (the “Bridge Notes”) and related accrued and unpaid interest for an aggregate amount of $73,630,210 (inclusive of amounts related to conversion of Bridge Notes and related accrued and unpaid interest) through the sale of Series B Preferred Units at an initial closing and several additional closings.

Each Series B Preferred Unit was converted into one Common Unit mandatorily upon the occurrence of the Corporate Conversion as outlined in the amended and restated Operating Agreement, and then subject to an 1:18 stock conversion pursuant to the terms of the plan of conversion for the Corporate Conversion. In connection with all Series B Preferred Unit closings, the Company issued warrants for the purchase of 35,452,084 Common Units at an exercise price of $1.25 per Unit, which expired unexercised upon the closing of the IPO. The Company also issued warrants to advisors for the purchase of 2,724,549 common units at an exercise price of $0.70 per Unit. The Company also issued 72,000 warrants to purchase common units with an exercise price of $1.25 per Unit, which expired upon the closing of the IPO. The fair value of these warrants to purchase common units were recorded within additional-paid-in-capital. In connection with the Corporate Conversion, the 2,724,549 warrants issued to advisors were converted to warrants to purchase 151,364 shares of common stock at an exercise price of $12.60 per share of common stock.

As of June 21, 2018, the Series B warrants that were issued to purchasers of the Bridge Notes were converted to (i) warrants to purchase 429,948 shares of common stock at an exercise price of $12.60 per share and (ii) the Series B Preferred warrants that were issued to financial advisors were converted into warrants to purchase 101,119 shares of common stock at an exercise price of $12.60 per share.

Note 16. Income Taxes

There is no provision for income taxes for the three and nine months ended September 30, 2019. The Company has incurred U.S. operating losses since inception and has not incurred any other income taxes. Prior to the Corporate Conversion on June 21, 2018, the Company was a limited liability company in the U.S., which is treated as a partnership for Federal and state income tax purposes. Accordingly, the Company was not subject to U.S. income taxes until its conversion.

Note 17. Warrant Liability

During the period ended June 30, 2017, the Company issued Bridge Notes together with associated warrants. Since the Bridge Note Warrants entitled the holders to purchase securities in the Qualified Equity Round at the purchase price payable for the related equity securities, the exercise price of the warrants was undetermined at the time of their issuance. Also, because the terms of redemption of the Series B Preferred Units were unknown at the time of their issuance as well as the deemed liquidation terms, the warrant liability was recorded at fair value and marked to market. The valuation of the warrant liability was determined using level 3 inputs. In connection with the Bridge Note closings, at the time of the Qualified Equity Round, the Company issued 7,739,092 Bridge Note Warrants all of which were outstanding as of March 31, 2018. At the time of the Corporate Conversion, these warrants were converted to warrants to purchase 429,948 shares of common stock at an exercise price of $12.60 and were reclassified to equity upon the determination that they no longer met the criteria to be classified as liabilities.

Note 18. Stock Based Compensation and Unit-Based Compensation

At the time of the Corporate Conversion, the issuance of common stock and options to purchase common stock to prior holders of Profits Interests in connection with the Corporate Conversion was accounted for as a type-1 modification of the old awards. See Note 15, Corporate Conversion and Equity, for detail on the conversion of awards under the previous LLC structure to the new corporate structure.

The following table presents the activity related to stock options for the nine months ended September 30, 2019. The options generally vest over a four-year period.

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding, January 1, 2019	2,228,904	$ 14.91	
Granted	1,325,177	6.40	
Exercised	—	—	
Cancelled	(1,198,715)	13.28	
Outstanding, September 30, 2019	2,355,366	$ 10.96	8.9

Valuation Information for Stock-Based Compensation

The fair value of each stock option award during the three and nine months ended September 30, 2019 was estimated at the grant date using the Black Scholes option pricing model with the following assumptions:

	Three months ended September 30, 2019	Nine months ended September 30, 2019
Risk-Free Interest Rate (%)	1.38 - 1.94	1.38 - 2.60
Expected Volatility (%)	102.66 - 103.79	78.97 - 103.79
Expected Term (Years)	5.0 - 6.1	0.7 - 6.2
Expected Dividend Yield (%)	0.0	0.0

The following table presents the activity related to restricted stock awards for the nine months ended September 30, 2019. The restricted stock granted generally vest over a four-year period:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding January 1, 2019	1,342,710	$ 15.00
Granted	204,088	6.88
Vested/Released	(313,104)	14.84
Cancelled	(92,903)	7.68
Outstanding, September 30, 2019	1,140,791	$ 11.18

The following table presents the activity related to restricted stock unit awards for the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2019	79,998	$ 15.00
Granted	1,317,174	2.59
Vested/Released	(58,800)	4.95
Cancelled	(92,057)	1.84
Outstanding, September 30, 2019	1,246,315	$ 3.02

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

	Three months ended September 30, 2019	Nine months ended September 30, 2019
Selling, general and administrative	$ 904,115	$ 2,030,465
Research and development	313,533	658,014
Cost of goods sold	1,927	1,927
	$ 1,219,575	$ 2,690,406

Total unrecognized compensation cost related to unvested awards as of September 30, 2019 was $7.4 million and is expected to be recognized over the next 2.7 years.

Note 19. Employee Stock Purchase Plan

Employee Stock Purchase Plan

On January 1, 2019, the Company adopted the 2019 Employee Stock Purchase Plan, which was approved by stockholder vote at the 2019 Annual Meeting of Stockholders held on June 7, 2019. The plan provides eligible employees of the Company with an opportunity to purchase common stock of the Company through accumulated payroll deductions, which are included in other current liabilities until they are used to purchase Company shares. Eligible employees participating in the bi-annual offering period can choose to have up to the lesser of 15% of their annual base earnings or the IRS annual share purchase limit of $25,000 in aggregate market value to purchase shares of the Company's common stock. The purchase price of the stock is the lesser of (i) 85% of the closing market price on the date of purchase and (ii) the closing market price at the beginning of the bi-annual offering period.

The maximum number of shares reserved for delivery under the plan is:

(a) 300,000 shares, plus

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

The common stock issuable in respect of the first bi-annual period under the plan were issued to eligible participating employees during the third quarter of 2019.

The following assumptions were used in the Black Scholes calculation of the fair value of the discount.

	2019
Dividend yield	0.0%
Risk-free interest rates	2.3%
Expected life (years)	0.06
Expected volatility	176%
Fair value	0.72

Compensation expense related to this plan was $1,426 and $22,053 for the three and nine months ended September 30, 2019, respectively. For the nine months ended September 30, 2019 employees purchased 28,802 shares.

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, the underwriters for the Company's IPO, and two stockholders of the Company. The plaintiffs each seek to represent a class of stockholders who purchased common stock of

the Company in its IPO or whose purchases are traceable to that offering. The complaints allege 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 complaints seek unspecified compensatory damages, interest, costs and attorneys' fees. 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. The Company filed a motion to dismiss the complaint on October 31, 2019.

In addition, 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 the underwriters for the Company's IPO. The plaintiffs each seek to represent a class of stockholders who (i) purchased common stock of the Company in its IPO or whose purchases are traceable to the IPO, or (ii) who purchased common stock of the Company 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 later public disclosures. The complaints seeks unspecified compensatory damages, interest, costs and attorneys' fees.

The Company intends to vigorously defend itself in the foregoing actions; however, in light of, among other things, the preliminary stage of these litigations, the Company is unable to provide any assurances as to the ultimate outcome of any of the lawsuits or 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.

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

Claim from Lifehealthcare Pty Ltd.

The Company was party to a joint venture arrangement (JV Arrangement) in Australia with Lifehealthcare Pty Ltd (LHP). In 2017, the parties agreed to terminate the JV Arrangement. In March 2019, the Company received a letter from LHP alleging certain breaches by the Company under the JV Arrangement, primarily arising out of the Company's alleged failure to notify LHP of the Company's IPO. The Company strongly disputes these allegations and notified LHP in writing in April 2019 of its position on this matter and its intent to vigorously defend itself against these claims. The Company has received no further communications from LHP in the intervening six months. Although no assurance can be given that LHP will not pursue this matter further, the financial impact, if any, in connection with any potential resolution of this matter is not expected to be material.

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. Restructuring Charges and Other Severance Related Charges

Restructuring charges

On May 29, 2019, the Company announced significant adjustments to the deployment of personnel and resources across the organization. The effort was intended to focus the Company on currently available and near-term revenue opportunities and on clinical programs specifically designed to expand the gammaCore product labeling. To achieve this goal, the Company has reduced the size of its organizational structure, including its field sales force and clinical operations.

The costs associated with this initiative primarily represent severance and other costs associated with employee terminations, the majority of which will be settled in cash, and totaled approximately $850,000. In June 2019, as part of this process, the

Company formally communicated the termination of employment to 31 employees, and as of September 30, 2019, the Company had terminated all of these employees. As of September 30, 2019, the Company has accrued liabilities of approximately $250,000 in connection with the remaining unpaid obligations related to the restructuring charges. The remaining obligation will be paid by the end of 2019.

Other Severance Related Charges

Officer Separation Costs

On June 10, 2019, Frank Amato, the Company's former Chief Executive Officer, offered his resignation. The Company entered into a Separation Agreement with Mr. Amato, pursuant to which he remained as Chief Executive Officer and a member of the Board until September 30, 2019 (the "Separation Date"). Pursuant to the Separation Agreement, Mr. Amato was paid $800,000 on October 1, 2019. In addition, all options to purchase Company common stock held by Mr. Amato continued to vest through the Separation Date and remain exercisable until the one-year anniversary of the Separation Date. All restricted stock units held by Mr. Amato continued to vest through the Separation Date.

Since Mr. Amato provided substantial services to the Company, the Company recognized all costs related to the Separation Agreement over the period from June 10, 2019 to September 30, 2019. In connection with the Separation Agreement, the Company recorded a charge of $800,000 for the nine months ended September 30, 2019.

Additional Executive Separation Costs

Effective July 31, 2019, the Company entered into a Separation Agreement with its Chief Commercial Officer. Pursuant to the agreement, a severance payment of $147,500 was recognized and is to be paid evenly over the subsequent six months. As of September 30, 2019, the remaining balance of approximately $100,000 has been accrued.

Note 22. Subsequent Events

Dissolution of Subsidiary

An inactive wholly owned subsidiary, electroCore Bermuda, Ltd., was dissolved in October 2019.

Appointment of New Chief Executive Officer and Member of the Board of Directors

Effective October 1, 2019, Daniel S. Goldberger was appointed the Company's Chief Executive Officer and to the Company's Board of Directors.

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, 2018 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 bioelectronic medicine company with a proprietary non-invasive vagus nerve stimulation, or nVNS, therapy. nVNS is a platform therapy that modulates neurotransmitters and immune function through its effects on both the peripheral and central nervous systems. We are initially focused on neurology and our therapy, gammaCore, is cleared by the U.S. Food and Drug Administration, or FDA, for use by adults for the following three neurology indications: the acute treatment of pain associated with each of migraine and episodic cluster headache; and the prevention of cluster headaches. In neurology, we intend to pursue further label expansions to include prevention of migraine. Finally, we are considering the potential for several new indications as our nVNS technology is being broadly studied in a number of investigator-initiated studies.

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

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

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

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

The first three clearances of our gammaCore therapy were facilitated by the FDA's creation of a new regulatory category: External Vagus Nerve Stimulator for Headache (21 CFR 882-5892). Based on this category's description, we anticipate that some additional label expansions may be possible through the pathway under Section 510(k) of the Federal Drug and Cosmetic Act. In July 2019, the FDA accepted for review our 510(k) premarket notification for a new indication for use of gammaCore for the prevention of migraine. Because the new indication of migraine prevention is supported largely by the Premium 1 study, which showed a trend in favor of gammaCore over a sham device in reducing the number of migraines per month but failed to achieve statistical significance, the FDA may not clear gammaCore for this use based on the Premium 1 results. In September 2019, the FDA asked for additional information regarding the 510(k) submission and we met with the FDA in November 2019 to discuss the nature of the requested information. In the meantime, we continue to enroll subjects in the Premium 2 clinical trial to support the label expansion for migraine prevention, if necessary, and to support the commercialization of gammaCore as a migraine prevention therapy should this indication receive FDA clearance. We expect to complete enrollment in Premium 2 in 2020.

Our Therapy Delivery Platform

gammaCore Sapphire is a prescription only handheld unit where patients self-administer discrete doses. After the initial prescription is filled, access to therapy is refilled monthly through the input of a unique, prescription-only authorization code.

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

We have never been profitable and have incurred net losses in each year since our inception. Our net loss from operations for the nine months ended September 30, 2019 and 2018 was approximately $36.6 million and $40.5 million, respectively. As of September 30, 2019, our accumulated deficit was $75.0 million. We expect to continue to incur substantial net losses and negative cash flows from operations for at least the next several years. We intend to continue to make targeted investments in building our U.S. commercial infrastructure. We also intend to continue to make targeted investments in research and development to expand our gammaCore therapy.

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

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

As of September 30, 2019, we had cash, cash equivalents and marketable securities of $33.5 million. Based on our available cash resources and cash flow projections, we believe we have sufficient funds to continue operations for at least the next 12 months and currently anticipate that there will be adequate resources to fund our operations into the beginning of 2021. See "—Liquidity Outlook."

Our Current Focus

On May 29, 2019, we announced significant adjustments to the deployment of personnel and resources across the organization. The effort was intended to focus our currently available and near-term revenue opportunities and on clinical programs specifically designed to expand the gammaCore product labeling. To achieve this goal, we have reduced the size of our organization, including our field sales force and clinical operations. We are currently focusing our resources on high-value geographic and other sales territories where the current prescriber base and regional payer coverage are most concentrated including:

(i) regional payers, some of whom have recently amended their policies to permit reimbursement for electroCore's principal offering, gammaCore who have covered lives that are highly concentrated in specific targeted geographic regions;

(ii) the Veterans Administration and Department of Defense, covered under the Federal Supply Schedule contract secured by the Company in December 2018, which has a significant patient population that can benefit from gammaCore;

(iii) the United Kingdom, where a recent award from the Innovative Technology Program of the National Health Service and potential guidance from the National Institute for Health and Care Excellence offers the potential to generate revenue from the treatment of cluster headache; and

(iv) other potential revenue opportunities, such as in workers compensation and personal automobile injury protection claims through our distribution agreement with Doctor's Medical, LLC announced in August 2019.

We have also postponed certain clinical trials in indications that are more exploratory in nature, such as our ATOM trial to pursue label expansion into migraine in adolescents and is also concentrating its resources on opportunities to broaden the gammaCore label to include migraine prevention. We have also reduced our medical affairs activities consistent with our current focus.

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 1 of our consolidated financial statements included elsewhere in this filing and our audited consolidated financial statements and related notes thereto for the year ended December 31, 2018 included in our Annual Report on Form 10-K filed with the SEC. Our consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States. Certain accounting policies involve significant judgments, assumptions, and estimates by management that could have a material impact on the carrying value of certain assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Recent Developments

Effective October 1, 2019, Daniel S. Goldberger was appointed Chief Executive Officer, and a member of our Board of Directors, replacing Frank Amato in both roles.

In July and August of 2019, purported stockholders of the Company filed separate class action lawsuits against the Company and its directors in the Superior Court of New Jersey. The plaintiffs allege certain violations of the securities laws in connection with the Company's initial public offering that occurred in June 2018. In addition, in September and October of 2019, purported stockholders of the Company served putative class action lawsuits in United States District Court for the District of New Jersey. The plaintiffs allege certain violations of the securities law in connect with the Company's initial public offering and certain later public disclosures. For more information about this and other pending litigation, see below in Part II, Item 1: Legal Proceedings.

Components of Our Results of Operations

Net Sales

US Commercial Payer Sales

We generate the majority of our net sales in the United States. In April 2017, we received FDA clearance for gammaCore for the acute treatment of pain associated with episodic cluster headache in adults. In January 2018, we received FDA clearance for gammaCore for the acute treatment of pain associated with migraine headaches in adults.

We implemented physician education and promotional programs with three goals: to provide patients therapy at no charge; to demonstrate to physicians the benefits of gammaCore therapy; and to prompt U.S. commercial payers to provide pharmacy benefit coverage for the product as a result of their observation of patient demand for the therapy.

Our current promotional program, *Partners for Coverage* allows eligible commercial insurance patients uninterrupted access to gammaCore for up to 12 months while insurance coverage is being pursued.

These programs have resulted in increases in prescriptions for gammaCore and has prompted negotiations with commercial payers, resulting in non-preferred medical and pharmacy reimbursement in approximately 10 million lives and medical exception coverage for an additional 30 million pharmacy benefit lives in the first quarter of 2019. Most of these prescriptions, however, have been for free goods, and the initiation of reimbursement by some of these organizations has been complex and slow to ramp up, thereby resulting in modest revenue growth. In May 2019 we reduced our field sales force until greater progress can be made with commercial payers.

Our goal had been to achieve a target of 100 million lives covered by the end of the first quarter 2020 from our commercial and government channels combined. Presently, we believe it is not likely we will achieve this goal. Due to the uncertainty of the amount and timing of achieving additional covered lives, we no longer intend to disclose a goal of covered lives. In addition, there is no guarantee that covered lives will translate into revenue or profitability for the Company.

We primarily sell to one specialty pharmaceutical distributor for our U.S. commercial payor sales.

Veterans Administration and Department of Defense

In January 2019, we announced that we had been awarded a five-year Federal Supply Schedule Medical Equipment and Supply contract, which makes gammaCore available to approximately 20 million lives whose care is administered by the Department of Veterans Affairs and the Department of Defense.

United Kingdom

On May 6, 2019, we announced that gammaCore was selected as one of eight innovative technologies by the National Health Service's Innovative Technology Payment. The award provides for additional reimbursement of gammaCore by the National Health Service.

On July 9, 2019, we announced that the United Kingdom's National Institute for Health and Care Excellence ("NICE") recently issued draft guidance regarding the use of gammaCore for cluster headache. The draft guidance highlights the potential economic savings of gammaCore and its potential to effectively treat cluster headache for approximately 25,000 people in the United Kingdom. NICE will solicit comments from stakeholders before issuing final guidance, which is expected to be published in December 2019.

We believe these developments offer the potential for revenue growth in the United Kingdom.

Other Potential Revenue Opportunities

In August 2019, we announced that we entered into an exclusive contract with Doctor's Medical, LLC for distribution rights to gammaCore for patients with workers compensation and automobile personal injury claims. In addition, we may consider partnerships, license, or distributor agreements with external parties to expand our sales and marketing capabilities.

Cost of Goods Sold

Cost of goods sold consists primarily of direct material, direct labor and overhead costs. A significant portion of our cost of goods sold consists of overhead costs such as quality assurance, warehousing and shipment, facilities, depreciation on

equipment and operations supervision and management. Due to our relatively low production volumes compared to our available assembling capacity, a large portion of our costs for our gammaCore therapy consists of overhead expense. If our production volumes increase as expected in the future, we anticipate that our per unit production costs will decrease.

Research and Development

Since our inception, we have focused significant resources on our research and development activities, including preclinical studies and clinical trials, activities related to regulatory filings, and manufacturing development efforts. Significant expenses also included in research and development are personnel costs, which includes compensation, benefits and stock-based compensation. We expense research and development costs as they are incurred.

Selling, General and Administrative

Our selling, general and administrative expenses consist primarily of personnel related costs (including compensation, benefits, and stock-based compensation) for executive, finance, administrative and field-based personnel, costs for commercial related infrastructure, and market development. As a result of clearance from the FDA and commencement of commercial sales in the United States, we incurred a significant increase in compensation costs as additional personnel were hired to oversee the execution of the commercial plan in the United States and Europe. Significant expenses include costs associated with marketing and advertising, salesforce, professional fees for legal services, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, rent, compliance, payor reimbursement development, accounting services, and consulting fees. Marketing costs include promotional costs which consist of free goods given to patients under our voucher and other free good programs to support potential future sales. The unit cost of these items is essentially identical to the unit cost of items flowing into Cost of Goods Sold, and consists of direct material, direct labor and overhead. In addition, the costs associated with the service provider for the voucher program is included in promotional costs as well.

On May 29, 2019, we announced significant adjustments to the deployment of personnel and resources across the organization, including our sales and marketing functions. For the foreseeable future, we expect general and administrative costs to be significantly less than costs prior to the cost reduction plan. The timing of possible future increased expenditures and their magnitude are primarily dependent on the commercial success and sales growth of gammaCore and gammaCore Sapphire. In addition, we expect to continue to incur general and administrative expenses in connection with being a public company, which may further increase when we are no longer able to rely on certain “emerging growth company” exemptions we are afforded under the JOBS Act.

Change in Fair Value of Warrant Liability related to Convertible Bridge Notes

The change in fair value of the warrant liability is based on revaluation of the liability during the five months and 20 days ended June 20, 2018. There were no warrant liabilities subsequent to June 20, 2018.

Income Taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred taxes are recognized based on the differences between financial statement and income tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. We provide a full valuation allowance on substantially all deferred tax assets. The provision for income taxes represents the current tax payable for the period and the change during the period in deferred tax assets and liabilities. We anticipate an immaterial provision given we are reporting losses in all our taxable jurisdictions and are recording a full valuation allowance on the net deferred tax asset. We recognize the effect of an income tax position only if, based on its merits, the position is more likely than not to be sustained on audit by the taxing authorities. Interest and penalties related to uncertain tax positions are recorded as income tax expense.

Net Income Attributable to Non-Controlling Interest

From our inception through September 30, 2019, we consolidated the financial results of our affiliate, electroCore (Aust) Pty Limited. Although we did not have a controlling ownership interest in electroCore (Aust) Pty Limited during that period, we determined that electroCore (Aust) Pty Limited was a variable interest entity, of which we were the primary beneficiary.

Results of Operations

Comparison of the three months ended September 30, 2019 to the three months ended September 30, 2018

The following table sets forth amounts from our consolidated statements of operations for the three months ended September 30, 2019 and 2018 with the changes in those items in dollars.

	For the three months ended September 30,		
	2019	2018	Change
	(in thousands)		
Consolidated statements of operations:			
Net sales	$ 683.0	$ 151.0	$ 532.0
Cost of goods sold	353.9	97.1	256.8
Gross profit	329.1	53.9	275.2
Operating expenses			
Research and development	2,274.9	2,333.3	(58.4)
Selling, general and administrative	8,143.4	11,272.4	(3,129.0)
Restructuring and other severance related charges	804.6	—	804.6
Total operating expenses	11,222.9	13,605.7	(2,382.8)
Loss from operations	(10,893.8)	(13,551.8)	2,658.0
Interest and other income, net	206.1	355.2	(149.1)
Other	—	(4.9)	4.9
Total other income/(expense)	206.1	350.3	(144.2)
Loss before income taxes	(10,687.7)	(13,201.5)	2,513.8
Provision for income taxes	—	2.4	(2.4)
Net loss from operations	(10,687.7)	(13,203.9)	2,516.2
Less: Net income attributable to noncontrolling interest	—	—	—
Total net loss attributable to Electrocore LLC and electroCore, Inc.	$ (10,687.7)	$ (13,203.9)	$ 2,516.2

Net Sales

Net sales were approximately $683.0 thousand and $151.0 thousand for three months ended September 30, 2019 and 2018, respectively. The increase of $532.0 thousand is due to increased selling efforts following the 2018 commercial launch of our products for the prevention and acute treatment of pain associated with episodic cluster headache and the acute treatment of migraine headache in adult patients. U.S. sales increased by $482.8 thousand, United Kingdom sales increased by $72.2 thousand.

Costs of Goods Sold

Cost of goods sold was approximately $353.9 thousand and $97.1 thousand for the three months ended September 30, 2019 and 2018, respectively. The lower cost of goods sold as a percentage of revenue is due to increased sales of gammaCore refill kits which have a lower cost structure than the gammaCore starter kits.

Research and Development

Research and development expense was approximately $2.3 million and $2.3 million for the three months ended September 30, 2019 and 2018, respectively. The slight decrease was primarily the result of a decrease in research activities, including reduced headcount and stock compensation expense as a result of our June 2019 reduction in force, offset by an increase in clinical study expenses.

Selling, General and Administrative

Selling, general and administrative expense was approximately $8.1 million and $11.3 million for the three months ended September 30, 2019 and 2018, respectively. The decrease of $3.2 million is primarily a result of our June 2019 reduction in force and other reduced sales and marketing expenses.

Restructuring and other severance related charges

Restructuring and other-related charges for the three months ended September 30, 2019 consist of severance related expenses. There was no such expense for the three months ended September 30, 2018.

Change in Fair Value of Warrant Liability and Derivative Instrument related to Convertible Bridge Notes

The change in fair value of the warrant liability is based on revaluation of the warrants and embedded derivative during the three months ended September 30, 2018, which occurred as a result of the corporate conversion in 2018. There was no warrant liability or embedded derivative during the three months ended September 30, 2019 as the result of the corporate conversion in 2018.

Interest and Other Income, Net

Interest and other income, net was $206.1 thousand and $355.2 thousand for the three months ended September 30, 2019 and 2018, respectively. This decrease of $149.1 thousand was the result of decreased interest and dividends from our portfolio of marketable securities.

Other expenses

Other expenses were $0 thousand and $4.9 thousand for the three months ended September 30, 2019 and 2018, respectively.

Comparison of the nine months ended September 30, 2019 to the nine months ended September 30, 2018

The following table sets forth amounts from our consolidated statements of operations for the nine months ended September 30, 2019 and 2018 with the changes in those items in dollars.

	For the nine months ended September 30,		
	2019	2018	Change
		(in thousands)	
Consolidated statements of operations:			
Net sales	$ 1,715.3	$ 625.4	$ 1,089.9
Cost of goods sold	766.2	386.5	379.7
Gross profit	949.1	238.9	710.2
Operating expenses			
Research and development	8,279.4	9,006.7	(727.3)
Selling, general and administrative	28,155.6	30,104.6	(1,949.0)
Restructuring and other severance related charges	1,997.3	—	1,997.3
Total operating expenses	38,432.3	39,111.3	(679.0)
Loss from operations	(37,483.2)	(38,872.4)	1,389.2
Change in fair value of warrant liability	—	(1,870.9)	1,870.9
Interest and other income, net	850.1	579.8	270.3
Other	(16.7)	(263.7)	247.0
Total other income/(expense)	833.4	(1,554.8)	2,388.2
Loss before income taxes	(36,649.8)	(40,427.2)	3,777.4
Provision for income taxes	—	2.4	(2.4)
Net loss from operations	(36,649.8)	(40,429.6)	3,779.8
Less: Net income attributable to noncontrolling interest	—	55.0	(55.0)
Total net loss attributable to Electrocore LLC and electroCore, Inc.	$ (36,649.8)	$ (40,484.6)	$ 3,834.8

Net Sales

Net sales were approximately $1.7 million and $0.6 million for nine months ended September 30, 2019 and 2018, respectively. The increase of $1.1 million is primarily due to increased selling efforts following the 2018 commercial launch of our products for the prevention and acute treatment of pain associated with episodic cluster headache and the acute

treatment of migraine headache in adult patients. U.S. sales increased by approximately $0.9 million, United Kingdom sales increased by approximately $0.2 million.

Costs of Goods Sold

Cost of goods sold was approximately $766.2 thousand and $386.5 thousand for the nine months ended September 30, 2019 and 2018, respectively. The increase of $379.7 thousand was the result of increased sales.

Research and Development

Research and development expense was approximately $8.3 million and $9.0 million for the nine months ended September 30, 2019 and 2018, respectively. The decrease of $0.7 million was the result of decrease in research activities as a result of our June 2019 reduction in force, offset by increase in clinical study expenses.

Selling, General and Administrative

Selling, general and administrative expense was approximately $28.2 million and $30.1 million for the nine months ended September 30, 2019 and 2018, respectively. The decrease of $1.9 million was the result of a decrease in sales and marketing costs of $2.2 million, largely due to our June 2019 reduction in force and other non-personnel related costs.

Restructuring and other severance related charges

The restructuring and other-related charges of $2.0 million during the nine months ended September 30, 2019 were due to the Company's restructuring plan implemented in June 2019 and other severance costs. There were no restructuring charges during the nine months ended September 30, 2018.

Change in Fair Value of Warrant Liability and Derivative Instrument related to Convertible Bridge Notes

The change in fair value of the warrant liability is based on revaluation of the warrants and embedded derivative during the nine months ended September 30, 2018, which occurred as a result of the corporate conversion in 2018. There was no warrant liability or embedded derivative during the nine months ended September 30, 2019.

Interest and Other Income, Net

Interest and other income, net was $850.1 thousand and $579.8 thousand for the nine months ended September 30, 2019 and 2018, respectively. This increase of $270.3 thousand was the result of returns on investments made with the proceeds from the IPO.

Other expenses

Other expenses, net was $16.7 thousand and $263.7 thousand for the nine months ended September 30, 2019 and 2018, respectively. The decrease of $247.0 thousand was due to a $250.0 thousand litigation charge during the nine months ended September 30, 2018 related to a litigation settlement in the first quarter of 2019, offset by warrant expense of $3.0 thousand in the nine months ended September 30, 2019, as part of such settlement.

Net Income Attributable to Non-Controlling Interest

Net income attributable to non-controlling interest was $0 and $55 thousand for the nine months ended September 30, 2019 and 2018, respectively. This income was due to the write-off of the previous liability from our joint venture in Australia in 2018.

Cash Flows

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

	For the nine months ended September 30,	
	2019	2018
	(in millions)	
Net cash (used in) provided by		
Operating activities	$ (36.0)	$ (34.9)
Investing activities	$ 34.5	$ (30.4)
Financing activities	$ 0.5	$ 78.4

Operating Activities

Net cash used in operating activities was $36.0 million and 34.9 million for the nine months ended September 30, 2019 and 2018, respectively. This increase in cash used in operating activities of $1.1 million was primarily due to changes in operating assets and liabilities partially offset by a decrease in net loss, as well as changes in the fair value of warrant liabilities and stock compensation due to the corporate conversion in June 2018.

Investing Activities

Net cash provided by investing activities was $34.5 million and used in investing activities was $30.4 million for the nine months ended September 30, 2019 and 2018, respectively. The increase reflects the net funds provided from the purchase, sale and maturities of marketable securities.

Financing Activities

Net cash provided by financing activities was $0.5 million and $78.4 million for the nine months ended September 30, 2019 and 2018, respectively. The decrease is a result of our 2018 issuance of common stock of $78.4 million, net of underwriting discount and other offering expenses, in connection with our IPO. During the nine months ended September 30, 2019 the Company received proceeds from a financing agreement to fund its directors and officers' insurance.

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. The Company has also entered into commitments for the purchase of component parts of inventory related to its gammaCore Sapphire launch as well as additional marketing related initiatives.

There are no material changes to the contractual obligations and commercial commitments, addressed in Note 10 in these quarterly financial statements, that were disclosed in the December 31, 2018 audited consolidated financial statements.

Liquidity Outlook

As of September 30, 2019, we had an accumulated deficit of $75.0 million. Historically, our primary sources of liquidity have been from private equity or debt offerings. In June 2018, we closed our IPO of 5,980,000 shares of common stock at a price of $15.00 per share with net proceeds of $77.5 million, after underwriting discount and other offering expenses. As of September 30, 2019, and December 31, 2018, our cash, cash equivalents, and marketable securities were $33.5 million and $68.6 million, respectively. As of September 30, 2019, and December 31, 2018, we had working capital (current assets less current liabilities) of $28.7 million and $65.6 million, respectively.

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. We also intend to continue to make targeted investments in research and development to expand our gammaCore therapy.

Based on our available cash resources and cash flow projections, we believe we have sufficient funds to continue operations for at least the next 12 months and currently anticipate that there will be adequate resources to fund our operations into the

beginning of 2021. If these projections are not achieved, we will have to further reduce discretionary non-personnel related spending to continue our operations into 2021. Until we can generate a sufficient amount of cash from operations, we expect to finance future cash needs through public or private equity or debt offerings. We filed a shelf registration statement on Form S-3 with the U.S. Securities and Exchange Commission, or SEC, which was declared effective on September 5, 2019. This registration statement will enable us to offer and sell to the public from time to time in one or more offerings, up to $50,000,000 of common and preferred stock, debt securities, warrants, units or any combination thereof. The terms of any securities offered under the registration statement, and the intended use of the net proceeds resulting therefrom, will be established at the times of the offerings and will be described in prospectus supplements filed with the SEC at the times of the offerings. There can be no assurance that we will be successful in securing additional capital in sufficient amounts and on terms favorable to us.

Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be unable to continue our operations at planned levels and be forced to further reduce or terminate our operations. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders and increased fixed payment obligations, and these securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Off-Balance Sheet Arrangements

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

Foreign Currency Exchange Risk

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

If the U.S. dollar uniformly increased or decreased in strength by 10% relative to the currencies in which our sales were denominated, our net income would have correspondingly increased or decreased by an immaterial amount for the three and nine months ended September 30, 2019.

Interest Rate Risk

Our exposure to market interest rate risk is confined to our cash and cash equivalents and marketable securities. As of September 30, 2019, we had cash and cash equivalents of $6.5 million and marketable securities of $26.9 million. 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 marketable securities, due to their very short-term nature, and are subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase or decrease in market rates would have any material negative impact on the fair value of our marketable securities or our interest income. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk.

All of the potential changes noted above are based on sensitivity analyses performed on our financial position as of September 30, 2019.

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 necessarily were required to 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 September 30, 2019 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 September 30, 2019, were effective for the purposes stated above.

Internal Control Over Financial Reporting

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation, as of September 30, 2019, the principal executive officer and principal financial officer concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective at the reasonable level of assurance.

Our principal executive officer and principal financial officer conducted an evaluation of our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) and have determined there are no changes in our internal controls over financial reporting during the quarter ended September 30, 2019, that have materially affected or which are reasonably likely to materially affect internal control over financial reporting.

Our management remediated the material weakness related to its internal control over financial reporting related to accounting for complex transactions that was disclosed in our prospectus dated June 21, 2018, filed with the SEC, pursuant to Rule 424(b) under the Securities Act.

Inherent Limitation on Effectiveness of Controls

Our management, including the Chief Executive Officer and Chief Financial Officer, believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, they cannot provide absolute assurance that all control issues and instances of fraud, if any, within electroCore have been prevented or detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by unauthorized override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Accordingly, because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Emerging Growth Company Status

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

For so long as we are an emerging growth company, we will not be required to provide an auditor’s attestation report on our internal control over financial reporting in future annual reports on Form 10-K as otherwise required by Section 404(b) of the Sarbanes-Oxley Act.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Stockholder 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, the underwriters for the Company's IPO, and two stockholders of the Company. The plaintiffs each seek to represent a class of stockholders who purchased common stock of the Company in its IPO or whose purchases are traceable to that offering. The complaints allege 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 complaints seek unspecified compensatory damages, interest, costs and attorneys' fees. 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. The Company filed a motion to dismiss the complaint on October 31, 2019.

In addition, 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 the underwriters for the Company's IPO. The plaintiffs each seek to represent a class of stockholders who (i) purchased common stock of the Company in its IPO or whose purchases are traceable to the IPO, or (ii) who purchased common stock of the Company 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 later public disclosures. The complaints seek unspecified compensatory damages, interest, costs and attorneys' fees.

The Company intends to vigorously defend itself in the foregoing actions; however, in light of, among other things, the preliminary stage of these litigations, the Company is unable to provide any assurances as to the ultimate outcome of any of the lawsuits or 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.

Claim from Lifehealthcare Pty Ltd.

The Company was party to a joint venture arrangement (JV Arrangement) in Australia with Lifehealthcare Pty Ltd (LHP). In 2017, the parties agreed to terminate the JV Arrangement. In March 2019, the Company received a letter from LHP alleging certain breaches by the Company under the JV Arrangement, primarily arising out of the Company's alleged failure to notify LHP of the Company's IPO. The Company strongly disputes these allegations and notified LHP in writing in April 2019 of its position on this matter and its intent to vigorously defend itself against these claims. The Company has received no further communications from LHP in the intervening three months. Although no assurance can be given that LHP will not pursue this matter further, the financial impact, if any, in connection with any potential resolution of this matter is not expected to be material.

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. The risk factors set forth below that are marked with an asterisk (*) are new or contain changes to the similarly titled risk factors included in Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, which was filed with the SEC on August 14, 2019.

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

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

We have experienced significant net losses, and we expect to continue to incur losses for the foreseeable future as we operate our sales and marketing infrastructure, increase market acceptance of our gammaCore therapy for the acute treatment of episodic cluster headache, or eCH, the prevention of cluster headache, and the acute treatment of migraine, 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 $36.6 million and $40.4 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, our accumulated deficit was $75.0 million. Our prior losses, combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders' deficit and working capital.

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

Even if we are able to increase sales of gammaCore, increase adoption of gammaCore therapy among physicians and payers and achieve desired payer coverage levels, we may not achieve profitability and even if we do, we may not be able to sustain or increase profitability in subsequent periods. If we fail to become profitable or are unable to sustain profitability, then we may be unable to continue our operations at planned levels and be forced to further reduce or terminate our operations. As of September 30, 2019, we had cash and cash equivalents of $6.5 million and marketable securities of $26.9 million. Based on our available cash resources and cash flow projections, we believe we have sufficient funds to continue operations for at least the next 12 months and currently anticipate that there will be adequate resources to fund our operations into the beginning of 2021. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

***We will be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all. **

Our operations have consumed substantial amounts of cash since inception, and we anticipate this continuing as we utilize our commercial sales force in the United States to increase adoption of gammaCore therapy with physicians and payers, potentially investigate the use of our gammaCore therapy for the treatment of additional new indications, including rheumatoid arthritis and Sjögren's syndrome, and continue to grow our business and transition to operating as a public company. We believe that our growth will depend, in part, on our ability to fund our commercial efforts for our gammaCore therapy for the acute treatment of eCH and the acute treatment of migraine, and to pursue research and development activities for additional indications for our gammaCore therapy. Our existing resources 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. For the nine months ended September 30, 2019 and 2018, net cash used in operating activities was $36.0 million and $34.9 million, respectively, and as of September 30, 2019 we had cash and cash equivalents of $6.5 million and marketable securities of $26.9 million. We expect that our existing capital resources, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Changes, including those relating to the payer and 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 and obtaining payer coverage
- the scope and timing of our investment in our U.S. commercial infrastructure and sales force;
- the costs of commercialization activities including sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of our gammaCore therapy;
- the outcome, timing of, and costs involved in, seeking and obtaining clearances or approvals from the FDA and other regulatory authorities, including the potential for the FDA and other regulatory authorities to require that we perform more studies, clinical trials or tests on our gammaCore therapy than we currently expect;
- the research and development activities we intend to undertake in order to expand our headache indications and enhancements to our gammaCore therapy that we intend to pursue;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence and acceptance of competing therapies or other adverse market developments.

To finance these activities, we may seek funds through borrowings or through additional rounds of financing, including public equity or debt offerings and collaborative arrangements with corporate partners. We may be unable to raise funds on favorable terms, if at all. We do not have any agreements or understandings with respect to any potential financing. Our low stock price, low market capitalization and trading volume may affect our ability to raise funds and the terms on which we will be able to raise funds. Our failure to obtain necessary financing could impair our ability to conduct our 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 may limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration Statement on Form S-3.

SEC regulations limit the amount that companies with a public float of less than $75 million may raise during any 12-month period pursuant to a shelf registration statement on Form S-3 (the “Baby Shelf Rule”). Although we are not currently limited by the Baby Shelf Rule, if our public float is below $75 million when we file an Annual Report on Form 10-K, we will not be able to use our shelf registration statement to raise more than one-third of our public float. Furthermore, if we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by the SEC staff.

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

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

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

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

We estimate that we have procured reimbursement from commercial payers for gammaCore in non-preferred medical and pharmacy reimbursement in approximately 10 million lives and medical exception coverage for an additional 30 million pharmacy benefit lives in the United States. In addition, we have an estimated 20 million covered lives under our contract with the Department of Veteran Affairs and the Department of Defense. There can be no assurance that we will maintain such existing coverage. Although we are negotiating contracts with additional insurance plans and PBMs, there can be no assurance that we will maintain such existing coverage. Our goal had been to achieve a target of 100 million covered lives by the end of the first quarter of 2020 from our commercial and government channels combined. Presently, we believe do not believe it is likely we will achieve this goal.

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

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

Applicable Medicare Part D regulations and federal and state laws will impose additional requirements on us upon execution of our commercialization strategy. Our commercialization strategy, including our planned reimbursement approach with respect to our gammaCore therapy, is likely to subject us to additional audit oversight requirements, and if material contractual or regulatory non-compliance were to be identified, applicable sanctions and/or monetary penalties may be imposed, which could have an adverse effect on our financial position, results of operations or cash flows.

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

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

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

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

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

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

Our primary commercialization strategy in the United States advocates for coverage and reimbursement for gammaCore under payers' pharmacy benefit. This pathway may allow patients to obtain our therapy through payment of a co-payment rather than being personally responsible for the costs of our product until meeting an annual deductible. While some commercial payers may provide coverage under their pharmacy benefit plans, other third-party payers, including government health programs and private insurers, may not be willing or able to cover gammaCore under pharmacy benefit plans, which are often limited to coverage of prescription drug products. For example, Medicare's voluntary pharmacy benefit, Medicare Part D, limits coverage under this benefit to prescription drugs, biologicals, and supplies used in the delivery of insulin, but does not cover medical devices like gammaCore or its supplies. Some commercial payers may determine to only provide coverage for gammaCore through the medical benefit pathway. While this would provide coverage for the therapy under a patient's medical benefit plan, patients may be unwilling to pay out of pocket for deductibles and co-pays for the therapy. Any determination by commercial payers to provide coverage for gammaCore through the medical benefit pathway and not through pharmacy benefit plans may delay or pose more risks to our commercial plan for gammaCore therapy since additional medical device codes may be required and the Company may incur additional direct and indirect expenses in assisting patients with their co-pay or other costs emergent from the determination by payers to not cover gammaCore under the pharmacy benefit pathway. Coverage by commercial payers through the medical benefit pathway or other decisions by commercial payers that have the effect of making patients personally responsible for the costs of, or costs associated with, our gammaCore therapy could adversely impact our results of operations and financial condition.

To obtain coverage and reimbursement from Medicare and any other third-party payer that will not cover gammaCore under a pharmacy benefit, we may be required to seek coverage and reimbursement as a medical device or item of durable medical equipment. If needed to obtain third-party payer coverage and reimbursement under an alternative benefit, these potential changes may entail numerous risks, including increased operating expenses, requirements to comply with healthcare regulatory laws, the loss of or delay in obtaining revenue, and uncertainty in our ability to successfully implement the modifications. The failure to obtain recognition by third-party payers under the pharmacy benefit model could require us to modify our commercialization strategy, our distribution model, our pricing, and our operations, any of which could have a material adverse effect on the sales of gammaCore and the results of our operations and financial condition.

We must demonstrate to physicians the merits of our gammaCore therapy compared to those of our competitors. *

Physicians play a significant role in determining the course of a patient's treatment and, as a result, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing our gammaCore therapy to physicians. While 510(k) clearance from the U.S. Food and Drug Administration (FDA) was received in

November 2018 for an expanded label for gammaCore therapy for adjunctive use for the preventive treatment of cluster headache in adult patients, such clearance does not necessitate adoption by physicians. In order for our gammaCore therapy to gain widespread adoption, we must successfully demonstrate to physicians the merits of our gammaCore therapy for the acute treatment of eCH and the acute treatment of migraine, compared to our competitors' products, for both prevention and acute treatment of migraine, including BOTOX marketed by Allergan plc and calcitonin gene-related peptide (CGRP) receptor agonists marketed by Amgen Inc. (with a co-marketing arrangement with Novartis International AG), Eli Lilly and Company, and Teva Pharmaceutical Industries Ltd. 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.

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

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

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

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

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

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

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

We rely on information technology and telephone networks and systems, including the internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales,

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

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

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

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

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

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

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

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

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

- the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations (Title 21 CFR);
- CE mark requirements of the European Union, or EU;
- Medical Device Quality Management System Requirements (ISO 13485:2003);
- Occupational Safety and Health Administration requirements; and
- New Jersey Department of Health Services requirements.

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

While 510(k) clearance from the U.S. Food and Drug Administration (FDA) was received in November 2018 for an expanded label for gammaCore therapy for adjunctive use for the preventive treatment of cluster headache in adult patients, our gammaCore therapy will remain subject to strict regulatory controls on manufacturing, marketing and use. We may be forced to modify or recall a product after release in response to regulatory action or unanticipated difficulties encountered in general use. Any such action could have a material effect on the reputation of our gammaCore therapy and on our business and financial position.

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

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

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

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

However, we face the risks that:

- We may fail to secure necessary patents, potentially permitting competitors to market competing products and services and make, use or sell products or offer services that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete.
- Patents may not issue from any of our currently pending or future patent applications.
- Our already-granted patents and any future patents may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us, and they may be challenged in a post grant review or inter partes review proceeding, re-examined or invalidated, and/or may be found to be unenforceable or not cover competing processes, products or services.
- Even if our patents are determined by the U.S. Patent and Trademark Office, or USPTO, foreign patent office, or a court to be valid and enforceable, they may not be drafted or interpreted sufficiently broadly to prevent others from marketing products and services similar to ours or designing around our patents. For example, third parties may be able to develop therapies, or make systems or devices, that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or

our contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights from third parties to issued patents or pending patent applications covering such technologies to allow us to commercialize our technology. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO to determine priority of invention in the United States. There may be prior public disclosures of which we are not aware that could invalidate our patents or a portion of the claims of our patents. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.

- Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications, our ability to obtain patents, or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations.
- Monitoring unauthorized uses of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors' therapies, products and services, and may in the future seek to enforce our patents or other proprietary rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product features, which could reduce demand for our gammaCore therapy. In addition, we may need to defend our patents from third-party challenges, including interferences, derivation proceedings, re-examination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions, or other patent proceedings. We may need to initiate infringement claims or litigation. Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable or may refuse to enjoin the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could place one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have patent portfolios, including significantly broader patent portfolios, to assert against us, if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.
- We may not be able to accurately estimate or control our future operating expenses in relation to obtaining, enforcing and/or defending intellectual property, which could lead to cash shortfalls. Our operating expenses may fluctuate significantly in the future as a result of the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.
- We may also be forced to enter into cross-license agreements with competitors in order to manufacture, use, sell, offer for sale, import and/or export products or services that are covered by our competitors' intellectual property rights. If we need to use our intellectual property to enter such cross-license agreements, it may compromise the value of our intellectual property due to the fact that our competitors may be able to manufacture, use, sell, offer for sale, import and/or export our patented technology.

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

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

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

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

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

In addition, the results of preclinical studies and early clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies or clinical trials for our gammaCore therapy in cluster and migraine headaches do not ensure that later preclinical studies or clinical trials will demonstrate similar results in other therapeutic indications, and it should be noted that we did not achieve the primary endpoints in our pivotal trials for cluster and migraine headaches. While 510(k) clearance from the U.S. Food and Drug Administration (FDA) was received in November 2018 for an expanded label for gammaCore therapy for adjunctive use for the preventive treatment of cluster headache in adult patients, there can be no assurance that the FDA and other regulatory authorities will be satisfied by data from our clinical trials for other treatment indications, even where we believe such data to be compelling. Our gammaCore therapy may fail to show the desired safety and efficacy traits in additional areas of indication in future clinical trials despite having progressed through preclinical and earlier stage clinical trials. Many companies in the pharmaceutical and medical device industries have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing clearance or approval of their products.

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

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

Conducting our prevention trial for our gammaCore therapy within the United States may subject us to additional costs and drawbacks, which may negatively impact our financial condition and our business. The costs of a foreign clinical trial (“FCT”) may be significantly lower than costs of an equivalent trial in the United States, as the materials and location costs of an FCT may be lower than a trial within the United States. Electing to run our prevention trial within the United States may impose significant added financial costs compared to a FCT. Among other factors, the faster recruitment of patients overseas and completion of trials in a FCT may represent considerable cost savings that we would forego in conducting clinical trials within the United States. These and other costs from conducting our planned prevention trial for our

gammaCore therapy instead of a FCT may negatively impact our financial condition and our business. In addition, a FCT may offer other non-financial benefits such as a larger potential population of qualified patients to participate in clinical trials compared against the potential enrollee population in the United States, where clinical trials may compete for a limited number of the same potential patients. These and other foregone benefits of a FCT may negatively impact our financial condition and our business.

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

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

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

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

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

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

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

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

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

In particular, in connection with the comprehensive redeployment plan and cost reduction implemented in June 2019, we have postponed certain clinical trials in indications that are more exploratory in nature and are concentrating our resources on opportunities to broaden the gammaCore label to include the prevention of migraine.

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

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

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

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

Even if our products are approved or cleared in the United States and European Economic Area, or EEA, (which is composed of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval and clearance procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our reorganization 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 36 employees and redeployed personnel and resources across our organization. The effort was intended to focus the Company 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 may 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 been growing the number of physicians willing to write prescriptions for our therapy and the number of prescriptions being written rapidly in recent periods and have a relatively short history of operating as a commercial company. We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, maintaining our direct sales force in the United States requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our commercialization and development goals.

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

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

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

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

In June 2019, we 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 and acute treatment of migraine headache in the United States and we may never achieve market acceptance.

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

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

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

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

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

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

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

Many of our current and potential competitors are publicly traded, or are divisions of publicly-traded, major pharmaceutical and medical device companies that have substantially greater financial, technical, sales and marketing resources than we do. We will face steep competition from Allergan plc, Amgen Inc., Novartis International AG and Teva Pharmaceutical Industries Ltd., among other established and potential competitors that may be better capitalized and have a history of commercializing products around the world. 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 cluster headache and migraine headache, future studies or patient experience over a longer period of time may indicate that treatment with gammaCore is less attractive than treatment with competitive products or that our gammaCore therapy causes unexpected or serious complications or other unforeseen negative effects. Such results would likely slow the adoption of our gammaCore therapy and significantly reduce our sales, which would harm our business and adversely affect our results of operations. Furthermore, if patients with traditional or other headache products were to experience unexpected or serious complications or other unforeseen effects, the market for our gammaCore therapy may be adversely affected, even if such effects are not directly attributable to our gammaCore therapy.

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

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

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

Sales of gammaCore outside the United States represented a substantial portion of our net sales in the nine months ended September 30, 2019 and 2018, respectively. In 2012, we began selling gammaCore in the EU through distributors. We sell gammaCore directly in 14 countries in the EU and through distributors and agents located in Munich, Germany and Leeds, UK. The sale and shipment of gammaCore across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws.

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

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

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

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

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

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

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

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

We believe that establishing and strengthening the electroCore and gammaCore brands is critical to achieving widespread acceptance of our gammaCore therapy to treat episodic CH, prevent cluster headache 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 to initially treat eCH, cluster headache prevention and migraine, may expose us to individual product liability claims, class action lawsuits or actions, and other individual or mass tort claims. Although we have, and intend to maintain, liability insurance, the insurers may deny our claims, coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. These risks are heightened in the event any product recalls take place as a result of any product design defect or defect in product warnings or labeling. Product liability claims could negatively affect our reputation, our continued product sales and our ability to obtain and maintain regulatory clearance or approval for our products.

An increase in products returns could negatively impact our operating results and profitability. *

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 addition, many of our employees have become or will soon become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Further, our employees' ability to exercise those options and sell their stock in a public market may result in a higher than normal turnover rate.

Our future success also depends on our ability to retain executive officers and other key employees and attract new key employees. Many executive officers and employees in the pharmaceutical and medical device industries are subject to strict non-compete or confidentiality agreements with their employers, which may include our main competitors. In addition, some of our existing and future employees are or may be subject to confidentiality agreements with previous employers. Our competitors may allege breaches of and seek to enforce such non-compete agreements or initiate litigation based on such confidentiality agreements. Such litigation, whether or not meritorious, may impede our ability to attract or use executive

officers and other key employees who have been employed by our competitors and may result in intellectual property claims against us. It is likely that we will experience similar aggressive lawsuit tactics by our competitors as they seek to protect their market position, particularly as we prepare to expand in new or existing markets.

***Our 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, or due to our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

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

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

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

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

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

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

We currently rely upon one specialty pharmaceutical distributor, who collaborates with a large network of specialty pharmacies, to distribute our products in the United States. We depend on this distributor to distribute our products but are unable to control its performance. This distributor may distribute a variety of other specialty pharmaceutical products that may limit the resources dedicated to the distribution of our products. In addition, we are unable to ensure that this distributor will comply with all applicable laws related to the distribution of our products. If this distributor fails to distribute our products in compliance with applicable laws, our operating results and business may suffer. Recruiting, training and retaining third-party distributors in the distribution of our proprietary product offerings requires significant time and resources. In addition, an affiliate of this distributor provides adjudication of prescriptions and reimbursement claims, pharmaceutical patient hub services, including patient support and training, for patients that are prescribed our gammaCore therapy, and has been electronically integrated with our proprietary data warehouse system and web portal. Our agreement with this distributor is scheduled to expire on November 30, 2019. We intend to extend this relationship past November 30, 2019. 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 Supply Schedule contractor subjects us to additional compliance and pricing requirements and may be withdrawn, which would make us ineligible to obtain certain federal government contracts and could negatively impact us and our business.

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

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

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

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

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaborations;

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

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

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

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

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

able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

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

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

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

Our gammaCore therapy consists of a substantial number of individual components. In order to market and sell effectively, we often must maintain high levels of inventory of the product and its components. As of September 30, 2019, we had approximately $5.1 million of inventory, as well as a commitment to purchase approximately $1.1 million of additional inventory by the end of 2019. In the aggregate, this amount significantly exceeds current demand for the gammaCore therapy.

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

Risks Related to Intellectual Property

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

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

The process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, some of our products are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use,

offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

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

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

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

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

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

- others may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents;

- we might not have been the first to conceive or reduce to practice the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for our inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable.

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

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

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

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

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

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

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- we or our collaborators may participate at substantial cost in International Trade Commission proceedings to abate importation of products that would compete unfairly with our products;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;

- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our products; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate its patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Regulation of our Industry

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

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

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

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

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

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

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the EU legislative bodies and the EEA Member States, Competent Authorities and notified bodies. The FDA and other U.S., EEA and foreign governmental agencies and authorities regulate and oversee, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;

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

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

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

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

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

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

Moreover, on May 25, 2017 the new Medical Devices Regulation (2017/745 or MDR) entered into force. Following its entry into application on May 26, 2020, the Regulations will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the EU Medical Devices Regulation repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA Member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA Member State laws implementing them, in all EEA Member States and are intended to eliminate current differences in the regulation of medical devices among EEA Member States. The EU Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The EU Medical Devices Regulation will however only become applicable three years after publication (in May 2020). Once applicable, the new regulations will among other things:

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

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

In order to continue to sell gammaCore in Europe, we must maintain our CE Mark and continue to comply with certain EU Directives and, in the future with the EU Medical Devices Regulation. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body (the British Standards Institution, or BSI), which could impair our ability to market products in the EEA in the future.

The United Kingdom's withdrawal from the EU ("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.

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

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to a legally marketed "predicate" device. 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 that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products internationally, we may be subject to rigorous international regulation in the future. In these circumstances, we would rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

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

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

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

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

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

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

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

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

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

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

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting, or MDR, requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or

failure to comply with regulatory requirements such as QSR may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

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

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

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

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

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

The FDA, EEA Competent Authorities and similar foreign governmental authorities have the authority to request or require the recall of commercialized products in the event of regulatory noncompliance or material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We must notify the FDA of all device recalls and corrections, and certain classifications of recalls and corrections require more extensive reporting within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls and corrections, even if they are not subject to more extensive reporting requirements. We may

initiate voluntary market withdrawals or other market actions involving our gammaCore products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls or corrections when they were conducted. Consumer class action claims and/or product liability claims are a greater risk following a product recall or market withdrawal.

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

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

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

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

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

Moreover, the policies of the Trump Administration and their impact on the regulation of our products in the United States remain uncertain. Political change could result in significant legislative and regulatory reforms impacting the FDA’s regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

In the EU, on May 25, 2017 the new Medical Devices Regulation (2017/745 or MDR) was adopted. Following its entry into application on May 26, 2020, the Regulations will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as

Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $74,792 (as the same may be adjusted for inflation) for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- in the event that third-party payers require us to be a durable medical equipment, or DME, supplier or we sell our products directly to providers who are DME suppliers that submit claims to such payers, we may be subject to the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including DME, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, civil monetary penalties of up to $24,253 (as the same may be adjusted for inflation) per claim submitted and exclusion from the federal health care programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA. The statute also provides for a penalty of up to $161,692 (and adjusted for inflation) for a circumvention scheme. Various states also have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state.
- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment of federal funds that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, which require certain applicable manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, or CHIP, to report annually to the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and

teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties of between $1,105 and $11,052 per failure (up to an aggregate of $165,786 per year), and between $11,052 and $110,524 per "knowing" failure (up to an aggregate of $1.105 million per year), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations; and

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

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

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

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. ACA, which was passed in 2010, substantially changed the way health care is financed by both governmental and private insurers and significantly impacts the U.S. healthcare industry. The ACA included, among other things, a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, effective January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. If reinstated, this excise tax would result in a significant increase in the tax burden on our industry, and if the efforts we would undertake to offset the excise tax are unsuccessful, the potential increased tax burden could have an adverse effect on our results of operations and cash flows. Other elements of the ACA, including comparative effectiveness research and payment system reforms, including shared savings pilots and other provisions, may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business.

We do not yet know the full impact that the ACA will have on our business. The taxes imposed by the ACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payers for our products, and/or reduced medical procedure volumes, all of which may have a material adverse impact on our business, financial condition, results of operations, or cash flows. Certain legislative changes to, and regulatory changes under, the ACA have occurred in the 115th Congress and under the Trump Administration. For instance, the Tax Cuts and

Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance beginning in 2019. Additional legislative changes to and regulatory changes under the ACA remain possible. Moreover, all or a portion of the ACA and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to certain providers, including hospitals.

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

Risks Related to Our Common Stock

Our failure to meet the continued listing requirements of the Nasdaq Stock Market ("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 the Company 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. If we do not regain compliance during this period, our stock could be delisted from Nasdaq. The failure to maintain our listing on Nasdaq could have an adverse effect on the liquidity and market price of our stock.

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

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

In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to our public company requirements. In particular, we incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the 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-Q 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 have broad discretion to determine how to use our financial resources, and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management has broad discretion over the use of our financial resources, including proceeds from our IPO, and 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 in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

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

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

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

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

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

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

As a public company, we are required to implement and maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following our IPO, which will be for our fiscal year ending December 31, 2019, provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an "emerging growth company," as defined by the JOBS Act. We do not expect to have our independent registered public accounting firm attest to our management report on internal control over financial reporting for so long as we are an emerging growth company. We are in the process of designing and implementing the internal control over financial reporting required to comply with this obligation, which process will be time consuming, costly and complicated.

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

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

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

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 September 30, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates, including Core Ventures II, LLC and Core Ventures IV, LLC, entities controlled by two of our directors, Joseph P. Errico and Thomas J. Errico, M.D., and Merck Global Health Innovation Fund, LLC, beneficially owned, including shares issuable upon the exercise or delivery of options, warrants, restricted stock units and deferred stock units that are currently vested or will vest within 60 days from the date hereof, an approximately 11 million shares of our voting stock which represents approximately 37% 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.

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

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

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

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act", or TCJA, that significantly reforms the Internal Revenue Code of 1986, or the Code, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures and puts into effect the migration from a "worldwide" system of taxation to a modified territorial system. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform on us and on holders of our common stock is uncertain and could be adverse. There can be no assurance that the TCJA will not negatively impact our operating results, financial condition, or our future business operations. This Report on Form 10-Q 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.

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

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

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 September 30, 2019, we used:

(i) approximately $6.8 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 $3.1 million to fund expansion of our clinical program into additional indications in headache and rheumatology,

(iii) approximately $2.8 million for the build out of our specialty distribution channel for the launch of gammaCore Sapphire, and

(iv) approximately $33.8 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) Not applicable.

(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 June 30, 2018 as filed with the Commission on August 14, 2018.)
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 June 30, 2018 as filed with the Commission on August 14, 2018.
10.1†	Amendment to Letter Agreement, dated August 8, 2019, between the Company and Brian Posner. (Incorporated by reference to Exhibit 10.2 to the Company Quarterly Report on Form 10-Q for the period ended June 30, 2019 as filed with the Commission on August 14, 2019.
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.

† Indicates management compensatory plan.

** 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: November 14, 2019

By: /s/ DANIEL S. GOLDBERGER

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

Date: November 14, 2019

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) [Omitted pursuant to Exchange Act Rules 13a-14(a) and 15d-15(a);]

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the 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: November 14, 2019

/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) [Omitted pursuant to Exchange Act Rules 13a-14(a) and 15d-15(a);]

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the 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: November 14, 2019

/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 September 30, 2019 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: November 14, 2019

/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 September 30, 2019 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: November 14, 2019

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