Risk Factors Comparison 2024-03-13 to 2023-03-08 Form: 10-K

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RISK FACTORS You should carefully consider the following risk factors, in addition to the other information in this Annual Report, including the section of this Annual Report titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this Annual Report occur, our business, operating results, and financial condition could be seriously harmed. This Annual Report also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of factors that are described below and elsewhere in this Annual Report. Risk Related to our Financial Position, Operating Results and Need for Additional ~~CapitalWe~~ -- **We will be required** to obtain additional funds in the future,and these funds may not be available on acceptable terms or at all.Our operations have consumed substantial amounts of cash since inception,and we anticipate this continuing for at least the next 12 months from the date the financial statements included in this Annual Report are made available as we continue seeking to invest in our business.We believe that our growth will depend,in part,on our ability to fund our commercial efforts for our ~~nVNS~~ - **VNS** platform technology,and to opportunistically pursue research and development activities for additional indications for our gammaCore therapy ~~.If our revenue continues to grow,it is likely we will have increased working capital needs in connection with increased inventory purchases and accounts receivable.Our ability to collect our accounts receivable on a timely basis is dependent on the intent and ability of our customers to pay on a timely basis~~ .There is no assurance that we will have sufficient cash flow and liquidity to fund our planned activities.As a result,we will need to seek additional funds in the future or curtail or forgo some or all of such activities.If we seek to and are unable to raise funds on favorable terms,or at all,we may not be able to support our commercialization efforts or increase our research and development activities,and the growth of our business may be negatively impacted.As a result,we may be unable to compete effectively.There is no assurance that we will generate sufficient funds through our operating results or financing activity thereby raising substantial doubt about our ability to continue as a going concern within one year of the date the financial statements included in this Annual Report.Changes,including those relating to the payor and competitive landscape,our commercialization strategy,our development activities,and regulatory matters,may occur beyond our control that would cause us to consume our available capital more quickly.Our future capital requirements will depend on many factors,including:• the outcome,timing of,and costs involved with negotiating,obtaining,maintaining,and enhancing payor coverage;• the outcome,timing of,and costs involved with our plan to potentially expand our direct- to- consumer,cash- pay business channel;• the scope and timing of our investment in our U.S.and UK commercial infrastructure and sales force;• the costs of commercialization activities including sales,marketing,manufacturing and distribution;• the costs incurred in defending against pending securities class- action litigations and other potential litigation,as well as the costs of any potential judgements or settlements;• the degree and rate of payor,physician,patient,and market acceptance of our ~~prescription~~ gammaCore therapy;• the degree and rate of consumer adoption of our non- prescription, ~~general~~ wellness product offerings;• the outcome,timing of,and costs involved in,seeking and obtaining clearances or approvals from the FDA and other regulatory authorities,including the potential for the FDA and other regulatory authorities to require that we perform more studies,clinical trials,or tests on our ~~prescription~~ gammaCore therapy than we currently expect;• the research and development activities we may undertake to expand our headache indications and enhancements to our ~~prescription~~ gammaCore therapy;• the costs of filing,prosecuting,defending,and enforcing any patent claims and other intellectual property rights;• the need for us and third parties,including payors and service providers,to potentially implement new or revised policies,infrastructure,and internal systems;• ~~the lead times,order quantities,and payment terms needed to purchase inventory;• our ability to collect accounts receivable on a timely basis;•~~ our ability to hire additional personnel to support our various functions and operations;and • the emergence and acceptance of competing therapies or other adverse market developments. ~~To~~ **17To** finance our activities,we may seek funds through borrowings or through additional rounds of financing,including public or private equity or debt offerings and collaborative arrangements with corporate partners.We may be unable to raise funds on favorable terms,if at all.We do not currently have any agreements or understandings with respect to any potential financing.Our stock price,market capitalization trading volume,and other macroeconomic factors may affect our ability to raise funds and the terms on which we will be able to raise funds.Our failure to obtain additional necessary financing could impair our ability to conduct our operations,and any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to (i) pursue our business plans and strategies and (ii) maintain our listing on the Nasdaq Stock Market. ~~11~~ In addition,our auditors report for our ~~2023~~ **2022** financial statements contains a statement concerning our ability to continue as a ~~"~~ **"** going concern ~~"~~ **"** .Our lack of sufficient liquidity could make it more difficult for us to secure additional financing terms acceptable to us,if at all,and may materially and adversely affect the terms of any financing that we may obtain and our stock price generally.Our ability to continue our operations depends upon,among other things,our ability to increase revenue,reduce operating expenses,and obtain additional funding through the sale of equity and / or debt securities,debt financing,strategic transactions,or otherwise.However,there are significant risks and uncertainties as to our ability to achieve these goals or to obtain required funding on commercially reasonable terms or at all,including as a result of the ~~potential~~ adverse impact on our business from **the ongoing COVID- 19 pandemic and other** macro- economic conditions.There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities,which could force us to significantly reduce or curtail our activities and ultimately potentially cease operations.The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders.If we borrow additional funds or issue debt securities,lenders or security holders could have rights superior to holders of our common stock,and such indebtedness could contain covenants that will restrict our operations **.We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies,therapeutic candidates,or products that we otherwise would not relinquish.If we do not obtain additional resources,our ability to capitalize on business opportunities will be limited and we may be unable to compete effectively,and the growth of our business would be materially and adversely harmed.** recently launched new cash pay initiatives, including our gConcierge and gCDirect programs, as well as our direct- to- consumer business channel and patients ~~and~~ **,** providers or consumers may be slow to adopt these programs or their pricing which could adversely impact our business and financial results. We currently have a cash- pay business channel for our **prescription** gConcierge and gCDirect programs ~~,~~ and ~~intend to expand our~~ direct- to- consumer business channel through **our** ~~the recently launched~~ ecommerce websites **. We intend to expand our direct- to- consumer business channel** by **continuing to** ~~increasing~~ **increase** our advertising and promotional activities in ~~2023~~ **2024** . This will require significant investment and expansion of our sales and marketing capabilities and further development by us relating to this business channel. We have limited experience with scaling and commercializing a direct- to- consumer cash- pay business channel in the United States and abroad, which may impact our ability to rely on this channel as a positive source of revenue. If we are unsuccessful in executing our commercialization efforts in our direct- to consumer business channel and do not achieve the sales levels that we reasonably anticipate to materialize in light of current planning and forecasting, we will be unable to recover the investments described above. Additionally, there is a risk that potentially lower pricing of our therapy in the direct- to- consumer cash- pay business channel could lead to lower pricing and reimbursement in our legacy business channels and, therefore, this risk could have an adverse impact on our financial position and results of operations as well as heighten our need to obtain additional financial capital to support our business projects. If third- party payors do not provide adequate coverage and reimbursement for the use of gammaCore, it may affect our ability to generate significant revenues. Some of our success in marketing and commercializing gammaCore depends, and will continue to depend, on whether U. S. and international government health administrative authorities, private health insurers, and other payor organizations provide adequate coverage and reimbursement for the cost of our products. Many third-party payors do not currently cover nVNS for any indications other than epilepsy because they have determined all other nVNS modalities to be investigational or experimental. If physicians or insurers do not find our clinical data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for gammaCore. We cannot provide assurance that data we or others may generate in the future will be consistent with data observed in our existing clinical studies, and we cannot provide similar assurance that our current or future published clinical evidence will be sufficient to obtain adequate coverage and reimbursement for gammaCore. Moreover, if we cannot obtain adequate coverage for and reimbursement of the cost of gammaCore, we cannot provide assurance that patients will be willing to incur the full cost of our **prescription** gammaCore therapy. Access to adequate coverage and reimbursement by third- party payors for our **prescription** gammaCore therapy or the willingness of patients to bear the entire cost of our therapy is essential in the acceptance of our gammaCore by physicians, patients, and other customers for our therapy. **12** ~~11Third~~ -- **Third** - party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for our **prescription** gammaCore therapy exists among third- party payors. Therefore, coverage and reimbursement for our **prescription** gammaCore therapy can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our **prescription** gammaCore therapy to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country- by- country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government- managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems and government- managed systems. If sufficient and timely coverage and reimbursement are not available for our current or future gammaCore products, or if reimbursement rates change, in either the United States or internationally, the demand for our gammaCore product and our revenues would be adversely affected. We have a limited history commercializing our ~~VNS~~ **nVNS** platform technology, including through direct- to- consumer channels, and commercial success is uncertain. **We** ~~Moreover, we~~ have limited experience engaging in direct- to- consumer commercial activities and limited established relationships with marketing agencies, analytic platforms, and social media following, all of which are becoming increasingly important to direct- to- consumer initiatives. We may be unable to gain broader market acceptance for our nVNS platform technology in our sales channels and markets, including direct- to- consumer channels in the United States or abroad, for a number of reasons, including: • established competitors with strong relationships with customers, including ecommerce and telehealth platforms, systems, marketing agencies and a critical mass of existing patients; • limitations in our ability to demonstrate differentiation and advantages of our product compared to our own products and competing products and the relative safety, efficacy and ease of use of our product; • the limited size of our marketing team and the learning curve required to gain experience selling our product direct- to- consumer; • limited brand awareness • insufficient financial or other resources to support our commercialization efforts necessary to reach profitability; and • the introduction and market acceptance of new, more effective or less expensive competing products and technologies in relevant geographic and product markets. We have a limited history commercializing our **general** wellness and human ~~performanceproducts~~ **performance products** in the United States for which market acceptance and commercial success are uncertain. As a small company with a limited history of selling our **general** wellness and human performance products, we have limited experience engaging in commercial activities and limited established relationships and experience with direct- to- consumer channels and third- party suppliers on whom we depend for the manufacture of our product components. In addition, as a general matter, we may fail to adapt our existing or future technology to patient and customer requirements or emerging treatment standards in our relevant geographic and product markets. New industry standards for the development, manufacture, and marketing of medical devices and general wellness products may evolve in separate ways, and we may not be able to conform to the changes, meet new standards in a timely fashion, or maintain a competitive position in our target marketplace. Moreover, if we face material delays in introducing our products and new technology, we may fail to attract new customers in part due to diminished brand awareness and ineffective implementation of marketing and promotion strategy. Specifically, we may be unable to successfully commercialize our **general** wellness and human performance products in the United States for a number of reasons, including: ~~12~~ **13** • established competitors with relatively more mature relationships with their customers and third- party suppliers; • limitations in our ability to demonstrate differentiation and advantages of our product compared to similar, competing products and the relative safety, efficacy and ease of use of our product; • the limited brand awareness of our Truvaga and TAC- STIM brands, which are our two recently launched non- prescription, **general** wellness and human performance products; • the limited size of our marketing budget to assess and increase customer demand levels; • the inability to obtain sufficient supply of the product components for our wellness products from our primary and secondary manufacturers and suppliers; • insufficient financial or other resources to support our commercialization efforts necessary to realize profitability; and • the introduction, and market acceptance, of new, relatively more effective, or less expensive, competing products and technologies. We **intend to launch our next generation app- enabled consumer wellness product under the brand Truvaga and there can be no assurance that the new product will be well received or adopted, which may impact our financial results. Our next generation app- enabled consumer wellness product has a new form factor and will be operated by a companion application. We have limited experience in launching app- enabled devices which is important to our direct- to- consumer initiatives. We may be unable to gain broader market acceptance for our new next generation app- enabled consumer wellness product in our direct- to- consumer channels in the United States or abroad, for a number of reasons, including: • established competitors with strong relationships with customers, including ecommerce and app- enabled devices, systems, marketing agencies and a critical mass of existing patients; • limitations in our ability to demonstrate differentiation and advantages of our product compared to our own products and competing products and the relative safety, efficacy and ease of use of our product; • the limited size of our marketing team and the learning curve required to gain experience selling our product direct- to- consumer; • limited brand awareness; • insufficient financial or other resources to support our commercialization efforts necessary to reach profitability; and • the introduction and market acceptance of new, more effective or less expensive competing products and technologies in relevant geographic and product markets. Our next generation app- enabled consumer wellness product may require modifications and improvements, which may cause added expense and negatively impact our financial results. If our next generation app- enabled consumer wellness product is not well received, we may need to make modifications or improvements including software updates, which may require additional research and development expense, or stop selling the new device all together which would negatively impact our financial results. Undiscovered vulnerabilities in our app- enabled wellness product could expose us or consumers to hackers or other unscrupulous third parties who develop and deploy viruses and other malicious software programs that could attack our products. Actual or perceived security vulnerabilities in our products could harm our reputation and lead some customers to return products, to reduce or delay future purchases, or use competing products. In addition, to the extent a competitor were to develop app- software that competes with ours, customers may choose not to purchase our wellness product. 14 We generate sales of TAC- STIM branded products to active- duty military and accordingly, military budgetary cuts or government strikes could negatively impact our financial results. We** recently launched our ~~Truvaga and~~ TAC- STIM branded products for ~~wellness and~~ human performance **within** ~~. Commercialization of these~~ -- **the active- duty military channel** ~~products may be very expensive, time consuming and may not generate favorable financial results~~ . **Funding** ~~We recently launched our business~~ for **purchases of** ~~wellness and human performance for our Truvaga and~~ TAC- STIM ~~branded products~~ - **product is subject to governmental budgetary decisions** ~~. We have limited experience in this area~~ and **any spending cuts may negatively impact the timing** ~~our~~ - **or amounts of** ~~initiatives may require significant investment to develop our~~ sales **to these customers, which could result in lost sales** and **harm our** ~~marketing capabilities for this~~ business ~~channel. If we are unsuccessful in executing our commercialization efforts in this business channel~~ and **operation results** ~~do not achieve the sales levels that we expect at all or within the time frames we have forecast, we may need to obtain additional financing on terms that may be dilutive or disadvantageous and we may be unable to recover these investments~~ . We have limited operating experience at our current scale of operations. If we are unable to manage our growth effectively, our brand, company culture, and financial performance may suffer. Implementation of our growth strategy for our gammaCore and human performance and **general** wellness products may require greater overall planned capital expenditures, and we cannot guarantee that any such increased expenditures will bring forth corresponding, offsetting revenue growth. Because we have a relatively limited history operating our business at its current and evolving scale, it is difficult for us to evaluate our present and future business prospects, including our ability to plan for, and model, future growth scenarios. Our limited operating experience at this scale, combined with the rapidly evolving customer demand and other market structure properties of the health and **general** wellness geographic and product markets in which we operate and other economic factors beyond our control, reduces our ability to accurately forecast quarterly or annual revenue. In particular, our ability to accurately forecast customer demand could be affected by myriad factors, including, without limitation, changes in customer demand levels for our products, changes in demand levels for the products of our competitors, the relative pace of acceptance of personalized health and **general** wellness recommendations, unanticipated weakening of various macroeconomic conditions, and capricious shifts in consumer confidence in future macroeconomic stability and / or the public capital markets. Failure to manage our future growth plans effectively could have an adverse effect on our financial condition and operating results. Any significant disruption to our ecommerce business could result in lost sales. **We recently** ~~In early 2022, we~~ launched new cash pay initiatives for our **Truvaga consumer product and prescription** gammaCore therapy, including our ecommerce websites in both the United States and United Kingdom. Online sales are subject to a number of risks. System interruptions or delays could cause potential patients to fail to purchase our products, harming our brands. Operating our direct- to- consumer ecommerce business depends on our ability to maintain the efficient and uninterrupted administration of online prescription generation, order- taking, and fulfillment activities. Our ecommerce operations subject us to certain risks that could have an adverse effect on our operating results, including risks related to the computer systems that operate our website and related support systems, such as system failures, viruses, denial of service attacks, computer hackers, data privacy breaches, and other disruptions. If we are unable to continually add software and hardware, effectively upgrade our systems and network infrastructure, and take other steps to improve the efficiency and efficacy of our systems, system interruptions or delays could occur that would adversely affect our operating results. We utilize third- party vendors for our customer- facing ecommerce technology, portions of our prescription generation, order management system, and fulfillment internationally. We depend on our technology vendors to manage " up- time " of the front- end ecommerce store, manage regulatory control measures around prescriptions, the intake of our orders, and export orders for fulfillment. Any failure on the part of our third- party ecommerce vendors, or in our ability to transition third- party services effectively, could result in lost sales and harm our business. ~~13We~~ **15 We** are subject to increasing operating costs and inflation risks, which may adversely affect our performance., While we may attempt to offset potential increases in operating costs through a variety of measures focused on increasing revenues or reducing operating expenses, there is no assurance that we will be able to do so. Therefore, operating costs may rise faster than associated revenues resulting in a material negative impact on our cash flow and margins. We are also impacted by inflationary pressures in wages in local and regional labor markets; structural labor market benefits, whether driven by competition for talent or ordinary course pay increases, and other rising costs. Increases in the rate of inflation could also significantly impact our cost base. In all countries in which we operate, wage inflation, whether driven by competition for talent or ordinary course pay increases, may also increase the cost of our cost products and adversely impact our results of operations and financial condition if we are not able to pass those costs on to our patients and consumers or charge premium prices when justified by actual or perceived market demand. Moreover, some of our existing or future customers may consider our products and services to be discretionary by nature. Factors affecting the aggregate level of spending for such customers possibly include current macroeconomic conditions, including inflation, consumer confidence in future macroeconomic conditions, fears of recession, the availability and cost of customer credit, rates of employment, and tax rates, which are factors that would adversely impact demand for our products. We have a history of significant losses. If we do not achieve and sustain profitability and positive cash flow from operations, our financial condition could suffer. Our failure to become and remain profitable could negatively impact the results of our operations as well as your investment. We have experienced significant net losses, and we expect to continue to incur losses for the foreseeable future while we operate our sales and marketing infrastructure, endeavor to increase acceptance of our **prescription** gammaCore therapy and ~~launch~~ **develop** our human performance and **general** wellness product line in relevant markets, fund our various research and development activities, and obtain regulatory clearance or approval for other products or indications in the United States and internationally. We have never been profitable and have incurred net losses in each year since our inception. We incurred net losses of $ **18. 8 million and $** 22 ~~. 2 million and $ 17~~ . 2 million for the year ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. As of December 31, ~~2022~~ **2023** , our accumulated deficit was $ ~~146~~ **165** . ~~4~~ **2** million. Our prior losses, combined with expected future losses, have had, and will continue to have for the foreseeable future, an adverse effect on our stockholders' deficit and working capital. To become and remain profitable, we must successfully commercialize our nVNS platform technology and identify promising areas of adoption with significant potential in terms of marketability, brand awareness, and product distinguishability, among other business considerations. This will require us to be successful in a range of challenging activities, which may include obtaining adequate coverage and reimbursement from payors; marketing and selling any current and future product candidates for which we may obtain appropriate marketing clearance, approval or authorization; developing commercial- scale manufacturing processes; managing various risks associated with the design, manufacture, marketing, and sale of human performance, **general** wellness product offerings, including compliance risk stemming from inadequate monitoring and analysis of applicable FDA and other relevant guidance as well as applicable consumer protection laws, rules, and regulations, ineffective initial and periodic assessment of claims and intended uses of such offerings, and inadequate government affairs, regulatory change management, or other corporate compliance functions that typically identify and remediate nonconformance with administrative law requirements, whether U. S. federal, state, or otherwise, and execute regulatory compliance processes more broadly; completing future clinical trials of gammaCore for additional therapeutic indications; obtaining additional marketing clearance, approval, or authorization from applicable regulatory authorities; militating against risk in, and enhancing the measures of cost efficiency in, our manufacturing; satisfying any post- marketing requirements; and developing the marketing and promotional expertise necessary to succeed in an integrative, well- funded direct- to- consumer approach through the sale of our **general** wellness and human performance product offerings. Because of the numerous risks and uncertainties associated with our commercialization efforts as well as our research and clinical development activities, we are unable to predict the timing or amount of increased expenses, or when, if ever, we will be able to achieve or maintain profitability. We expect to continue to incur substantial net losses and negative cash flows from operations as we commercialize our nVNS platform technology. We intend to continue to make targeted investments in building our U. S. and UK commercial infrastructure. ~~14If~~ **16 If** we fail to become profitable or are unable to sustain profitability, then, we may be unable to continue our operations at planned levels and may be forced to further reduce, or ultimately terminate, our operations. As of December 31, ~~2022~~ **2023** , we had cash ~~and~~ **,** cash equivalents and ~~marketable securities~~ **restricted cash** of $ ~~18~~ **10** . ~~0~~ **6** million. There can be no assurance that we will have sufficient cash flow and liquidity to fund our planned activities, which could force us to significantly reduce or curtail our activities and ultimately and potentially cease operations. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development and marketing efforts, and expand our business or continue our operations. Accordingly, a decline in the market value of our company could cause you to lose all or part of your investment ~~. Our plans to expand our direct- to- consumer cash- pay business channel may not be able to generate significant revenues. We currently have a small direct- to- consumer cash- pay business channel, which we are planning to expand in 2023 and beyond. This will require significant investment in, and expansion of, our sales and marketing capabilities and use of our own ecommerce platform, as stated previously. If we are unsuccessful in executing our commercialization efforts in this business channel and do not achieve the sales levels that we expect in light of our current plans and forecasts, we may be unable to recover these investments. Additionally, there is a risk that expanding our direct- to- consumer cash- pay business channel could erode demand for our prescription products, depress pricing with third- party payors and, therefore, have an adverse impact on our results of operations~~. We must successfully attract, hire, train, and retain qualified professionals to service our direct- to- consumer sales channels, and we must productively deploy our professionals to become profitable. Identifying, recruiting, hiring, and retaining professionals, including employees, independent contractors, and consultants with diverse skill sets across our broad geography of operations consistent with servicing our existing, new, and evolving sales channels, including direct- to- consumer are critical to our sales strategy. The market for qualified professionals is evolving, dynamic, and increasingly challenging. Our corporate reputation is a significant factor on consumers' evaluation of whether to buy our products and on potential employees' evaluation of whether to join our company. If we are unable to recruit skilled professionals, and if we do not deploy those professionals productively, our results of operations may be adversely impacted. We must manage our sales and marketing team well and plan and train for future needs effectively while accurately predicting physician, patient, and consumer demand. We may not be able to retain such talented professionals long- term for a variety of reasons, including their desire to remain as independent content creators rather than full- time employees. If we are unable to attract, hire, train, and retain highly skilled professionals and productively deploy them on our sales and marketing efforts, we will jeopardize our ability to develop ongoing and future sales, which could adversely affect our financial condition and results of operations. Competition for highly skilled professionals is intense in the markets where we operate, and we may experience significant employee turnover rates due to such competition. If we are unable to retain professionals with specialized skills, our revenues, operating efficiency, and profitability would decrease. Cost reductions, such as reducing headcount, or voluntary departures that result from our failure to retain the professionals we hire, could negatively affect our reputation as an employer and our ability to hire skilled professionals to meet our business requirements. Increased compensation to retain skilled professionals could lead to lower margins or higher costs and price increases that could in turn lead to a general reduction in demand levels for our products. Any significant growth in the market for our products and services or our entry into a new market may require an expansion of our employee base for managerial, marketing, operational, financial, and other purposes. During any period of growth, we may face problems relating to our operational and financial systems and controls, including quality control and delivery and service capacities. We would also need to continue to expand, train, and manage our employee base. Continued future growth will impose significant added responsibilities upon the members of management to identify, recruit, maintain, integrate, and motivate new employees. Our consultants and certain of our sales force are classified as independent contractors, and we can face consequences if it is determined that they are misclassified as such. There is often uncertainty in the application of worker classification laws, and, consequently, there is risk that our independent contractors could be deemed to be misclassified under applicable law. The tests governing whether a service provider is an independent contractor or an employee are typically highly fact- intensive and vary by jurisdiction. Laws and regulations that govern the status and misclassification of independent contractors are also subject to divergent interpretations by various authorities, which contributes to uncertainty or unpredictability in the law. A misclassification determination or allegation creates potential exposure for us, including, but not limited to, monetary exposure arising from or relating to failure to withhold and remit taxes, unpaid wages, and wage and hour laws and requirements (such as those pertaining to minimum wage and overtime); claims for employee benefits, social security, workers' compensation and unemployment; claims of discrimination, harassment, and retaliation under civil rights laws; claims under laws pertaining to unionizing, collective bargaining, and other concerted activity; and other claims, charges, or other proceedings under laws and regulations applicable to employers and employees, including risks relating to allegations of joint employer liability. Such claims could result in monetary damages (including, but not limited to, wage- based damages or restitution, compensatory damages, liquidated damages, and punitive damages), interest, fines, penalties, costs, fees (including, but not limited to, attorneys' fees), criminal and other liability, assessment, or settlement. Such an allegation, claim, adverse determination, including but not limited to with respect to advisors and consultants that provide services to us, could also harm our brand and reputation, which could in turn adversely impact our business. ~~15If~~ **17 If** we experience price fluctuations for our products, and we are unable to reduce our expenses, including the per unit cost of producing our products, there may be a material adverse effect on our business, results of operations, and financial condition. We anticipate that we will experience price fluctuations for our products due to pricing pressure relating to our efforts to increase consumer demand for our products. We may also face pricing pressure from managed care organizations and other third- party payors due to increased market power of our payors while the medical device industry consolidates as well as increased competition among suppliers, including manufacturing services providers. If the prices for our products decrease, and we are unable to reduce our expenses, including the cost of sourcing materials, logistics, and the cost to manufacture our products, our sales, results of operations, financial condition and cash flows, could be adversely affected. Macroeconomic conditions may result in increased costs for manufacturing and outsourced services and cause additional pressure to reduce the prices for our products if a recession or depression occurs, and people are unable to afford our products. ~~We cannot predict the ultimate impact that the ongoing COVID- 19 pandemic and its effects and macro- economic conditions could have on our business operations~~

~~and financial condition.~~ Any increased or unexpected pricing pressures, costs, delays, or failures to achieve cost savings, and unexpected risks we encounter in our business, including those caused by factors outside our control, could adversely affect our business, results of operations, financial condition and cash flows **. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, bank failures, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID- 19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the global capital markets. Similarly, the current Russia- Ukraine war, and other conflicts including military activities in the Red Sea and Persian Gulf as well as those relating to the Gaza Strip and Israel, may exacerbate volatility in the global capital markets or disrupt the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs, including personnel costs. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition** . Future acquisitions, strategic investments, or alliances could disrupt our business and harm our business, financial condition, and operating results. We may in the future explore potential acquisitions of companies and technologies, strategic investments, or alliances to strengthen our business. Acquisitions involve numerous risks, any of which could harm our business, including: • regulatory hurdles; • anticipated benefits may not materialize; • cultural challenges associated with integrating employees from the acquired company into our organization; • various challenges with regard to the acquired company ~~'~~ **'** s products and technology in the existing internal corporate and customer facing systems or processes; • integration of the acquired company ~~'~~ **'** s accounting, management information, human resources, and other administrative systems or processes; • the need to implement or improve controls, procedures, and policies in a preexisting business organization that, prior to the acquisition, may have lacked effective controls, procedures, and policies; • coordination of product development and sales and marketing functions; • liability for activities of the acquired company before the acquisition, including relating to privacy and data security, patent and trademark infringement claims, violations of laws, commercial disputes, tax liabilities, and other known and unknown liabilities; and • litigation or other claims in connection with the acquired company, including claims from terminated employees, users, former stockholders or third parties. Failure to appropriately mitigate these risks or other issues related to such acquisitions and strategic investments could result in reducing or completely eliminating any anticipated benefits of transactions, and harm our business generally. Future acquisitions could also result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, amortization expenses or the impairment of goodwill, any of which could harm our business, financial condition, and operating results. **18** We will be required to obtain additional...... would be materially and adversely harmed. Risks Related to Our Business **Regulatory** ~~and the Development of Our gammaCore TherapyRegulatory~~ requirements and changes to payors' prescription benefit plans and medical pathway plans could adversely impact our business and financial results ~~. While we have ongoing discussions with the Centers for Medicare and Medicaid Services, our products are not currently covered by Medicare and Medicaid~~ . Applicable Medicare Part D regulations and federal and state laws will impose additional requirements on us upon execution of our commercialization strategy. Our commercialization strategy, including our planned reimbursement approach with respect to our **prescription** gammaCore therapy, is likely to subject us to additional audit oversight requirements, and if material contractual or regulatory non- compliance were to be identified, applicable sanctions and / or monetary penalties may be imposed, which could have an adverse effect on our financial position, results of operations, or cash flows. In time, changes in payor prescription benefit plans or medical pathway plans could have the effect of rendering existing pharmacy benefit plans or medical pathway plans less valuable to beneficiaries and reduce the total market for our **prescription** gammaCore therapy. In addition, some payors could decide to discontinue providing full or partial coverage to their members for our **prescription** gammaCore therapy, which could have an adverse effect on our financial position, results of operations, or cash flows. ~~18Our commercialization strategy of gammaCore may expose us to increased billing, cash application, and credit risks.~~ Our commercialization strategy **of gammaCore may expose us to increased billing, cash application, and credit risks. Our commercialization strategy** may involve funding for our **prescription** gammaCore therapy through medical benefit coverage, the majority of which is provided by private insurers, as well as reimbursement by government agencies. Such claims are generally for very high- priced medicines, and collection of payments from insurance companies, patients, and other payors generally takes substantially longer than for those claims administered through a pharmacy benefit manager. Because of the high cost of these claims, complex billing requirements, and the nature of the medical benefit coverage determination process, these accounts receivable are characterized by higher risk in collecting the full amounts due and applying the associated payments. In addition, possible sales in our EUA business channel to hospitals may involve higher credit risks than sales to other payors. Revenues from the sale of our **prescription** gammaCore therapy partially depend on the continued availability of reimbursement by government and private insurance plans. The government' s Medicare regulations are complex, and, as a result, the billing and collection process is time- consuming and typically involves the submission of claims to multiple payors whose payment of claims may be contingent upon the payment of another payor. Because of the coordination with multiple payors, and the complexity in determining reimbursable amounts, these accounts receivable have higher risk in collecting the full amounts due and applying the associated payments. Our **prescription** 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. **We expect a portion of our 2024 sales will be made pursuant to the distribution agreement with Lovell Government Services (" Lovell ") and their contract vehicles. As a result of this relationship an increasing portion of gammaCore therapy sales in the government channel will be processed through Lovell and payment made to us by Lovell according to the terms of the Lovell distribution agreement.** Additionally, we may be subject to increased credit risk associated with state and local government agencies experiencing increased fiscal challenges. As a result of the aforementioned risks, our commercialization strategy, even if successful, may involve ~~recordation~~ **the incurrence** of bad debt expenses potentially impacting our results of operations and liquidity. **Any payment delays or disputes in our relationship with Lovell could have an adverse effect on our results of operations and financial condition. 19** Third- party payors have been resistant to cover gammaCore through pharmacy benefit plans, which has hindered our commercialization strategy and required changes to our existing business that could delay and negatively impact our ability to generate revenue. In the United States, our initial strategy to obtain reimbursement for gammaCore under payors' pharmacy benefit has not achieved adequate coverage and reimbursement. To obtain coverage and reimbursement from Medicare and any other third- party payor that will not cover gammaCore under a pharmacy benefit, we are seeking coverage and reimbursement as a medical device or item of durable medical equipment. While this would provide coverage for the therapy under a patient' s medical insurance, patients may be unwilling to pay out of pocket for deductibles and co- pays for the therapy. Any determination by commercial payors to provide coverage for gammaCore through the medical benefit pathway and not through pharmacy benefit pathway will further delay or pose more risks to our commercial plan for **prescription** gammaCore therapy since additional medical device codes are required, and we may incur additional direct and indirect expenses in assisting patients with their co- pay or other costs emergent from the determination by payors to not cover gammaCore under the pharmacy benefit pathway. Coverage by commercial payors through the medical benefit pathway or other decisions by commercial payors that have the effect of making patients personally responsible for the costs of, or costs associated with, our **prescription** gammaCore therapy could adversely impact our results of operations and financial condition. These potential changes may entail numerous risks, including increased operating expenses, requirements to comply with healthcare regulatory laws, the loss of or delay in obtaining revenue, and uncertainty in our ability to successfully implement the modifications. The failure to obtain recognition by third- party payors under the pharmacy benefit model has required us to modify our commercialization strategy, our distribution model, our pricing, and our operations, any of which could have a material adverse effect on the sales of gammaCore and the results of our operations and financial condition. ~~19We~~ **We** must demonstrate to patients, physicians, and third- party payors the medical and economic benefits of our **prescription** gammaCore therapy compared to those of our competitors or other available therapies, and such comparisons may not be realizable. Physicians play a significant role in determining the course of a patient' s treatment and, as a result, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing our **prescription** gammaCore therapy to physicians. We have received several 510 (k) clearances from the FDA for **prescription** gammaCore therapy; however, such clearances do not necessitate adoption by physicians. In order for our **prescription** gammaCore therapy to gain widespread adoption, we must successfully demonstrate to physicians the medical and economic benefits of our **prescription** gammaCore therapy compared to competitors' products, including (i) BOTOX marketed by Allergan plc, (ii) CGRP receptor agonists marketed by Amgen Inc. (with a co- marketing arrangement with Novartis International AG), Allergan plc, Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., and Pfizer Inc., (iii) lasmiditan, marketed by Eli Lilly, (iv) Vycpti, an intravenous preventive treatment for migraine marketed by H. Lundbeck A / S, and (v) neuromodulation devices that have been marketed for the acute treatment and / or prevention of migraine, including the Cefaly ~~and~~ **,** Nerivio **, and Savi Dual** devices. We also may face challenges because noninvasive VNS, or nVNS, is relatively new compared to existing traditional treatments for cluster and migraine headaches. **20** Acceptance of our **prescription** gammaCore therapy depends on educating patients and physicians as to the distinctive characteristics, perceived benefits, safety, ease of use, and cost- effectiveness of our **prescription** gammaCore therapy relative to our competitors' products and communicating to physicians the proper use of our **prescription** gammaCore therapy. If we are not successful in convincing patients and physicians of the merits of our **prescription** gammaCore therapy or educating them on the benefits of our **prescription** gammaCore therapy, they may not seek a prescription or prescribe our **prescription** gammaCore therapy, and we may be unable to increase our sales, sustain our growth, or achieve profitability. In addition, we believe support of our products by physicians is essential for market acceptance and adoption. If we do not receive support from physicians, or long- term data do not show the benefits of using our **prescription** gammaCore therapy, patients and physicians may not use it. In such circumstances, our results of operations would be materially and adversely affected. We must demonstrate to customers the benefits of nVNS platform technology for general ~~wellbeing~~ **wellness** and human performance compared to those of our competitors and such comparisons may not be realizable. Consumer sentiments play a significant, and increasing, role in determining customer adoption of certain **general** wellness products. In general, our success depends on the continued willingness of consumers to use health and **general** wellness products and services and to place value in the primacy of scientific evidence in the marketing of **general** wellness products and services. To be successful, we will need to continue to significantly invest in educating consumers about our products. This need is elevated in the light of the health and **general** wellness market' s particular characteristics. The market is heavily saturated, and the expected future demand for and market acceptance of innovative products and services in the market ~~are~~ **is** uncertain. While we believe it is reasonable to predict that the overall health and **general** wellness market will continue to grow, it is difficult to predict the future growth rates, if any, of certain sectors that intersect with comparable and substitution products relevant to our business. As a result, if our market does not further develop, or develops more slowly than expected, or becomes saturated with competitors with greater financial or other resources, or if our products do not achieve sufficient adoption in accordance with present and future business plans, our financial condition, and operating results could be materially and adversely affected. In particular, as stated previously, acceptance of our nVNS platform technology depends on educating patients as to the distinctive characteristics, perceived benefits, safety, ease of use, and cost-effectiveness of our nVNS platform technology relative to our competitors' products and communicating to customers the proper use of our nVNS products. As a result, our success depends, in large part, on effectively marketing our nVNS platform technology to consumers. For our nVNS platform technology to gain widespread adoption, we must successfully demonstrate to consumers the relative benefits of our nVNS platform technology compared to competitors' products. We also may face challenges because nVNS is relatively new compared to existing **general** wellness products across a multitude of price points. Further, the competitive landscape for **general** wellness products is crowded and continues to rapidly evolve. Therefore, our **general** wellness business line faces a diverse set of challenges that may have a significant effect on your investment. Stimulating therapeutically relevant fibers in the vagus nerve by a proprietary high- frequency burst waveform that passes through the skin cells represents a novel approach to treating pain, and we must overcome significant challenges to successfully develop, commercialize, and manufacture our product. We have concentrated our development and commercialization efforts on products based on a platform of stimulating therapeutically relevant fibers in the vagus nerve by a proprietary high- frequency burst waveform that passes through the skin. We believe that our product platform represents a novel approach to treating pain. However, to date, the FDA has cleared only our gammaCore products for commercialization based on this platform. The processes and requirements imposed by the FDA or other applicable health authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our gammaCore products. Because our platform is novel, regulatory agencies, as well as insurance and other coverage providers and payors, may lack experience in evaluating product candidates like gammaCore and gammaCore Sapphire. This inexperience may lengthen the regulatory review process, increase our development costs, and delay or prevent reimbursement and commercialization of our platform products. Additionally, advancing this novel platform creates significant challenges for us, including: ~~20~~ **21** • training a sufficient number of medical personnel on how to properly administer our product; • enrolling sufficient numbers of patients in future clinical trials; • manufacturing our products on a large scale and in a cost- effective manner; • submitting applications for and obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of our product platform for treating pain; and • establishing sales and marketing capabilities as well as developing a manufacturing process and distribution network to support the commercialization of any approved products. We must be able to overcome these challenges in order to successfully develop, commercialize, and manufacture our gammaCore and product candidates. Our operating results may vary significantly from quarter to quarter because of seasonality, bulk orders, shipments to distributors, or otherwise. Our quarterly revenue and results of operations may fluctuate from quarter to quarter due to, among others, the following reasons: • physician and payor acceptance of our **prescription** gammaCore therapy; • patients' acceptance of our nVNS platform technology ~~gammaCore therapy~~ ; • customer acceptance of our **general** wellness and **human** performance products **; • the timing and amount of TAC- STIM sales** ; • payor adoption; • estimated useful life of products; • the timing of when individual payor coverage becomes available; • patient and physician product returns; • the timing, expense, and results of research and development activities, future clinical trials, and regulatory clearance or approvals; • fluctuations in our expenses associated with expanding our commercial operations and operating as a public company; • fluctuations in our marketing spend to drive patient purchases; • the introduction of new products, therapies, and technologies by competitors; • the productivity of our field sales function; • supplier, manufacturing, or quality ~~problems~~ **issues** 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 **; • timing of working capital requirements** ; • adverse developments in coverage amounts, benefit pathway, or government and third- party payors' reimbursement policies; and • the timing of customer budget cycles. **22** ~~21Our~~ -- **Our** results may also fluctuate on a seasonal basis due to the seasonality of cluster and migraine headache attacks, which could affect the comparability of our results between periods. These seasonal variations are difficult to predict accurately, may vary across different markets, and at times may be entirely unpredictable, which introduce additional risk into our business because we may rely upon forecasts of customer demand to build inventory in advance of anticipated sales. In addition, we believe our limited commercial history has, in part, made our seasonal patterns more difficult to discern, making it more difficult to predict future seasonal patterns. We derive a material portion of our revenue **made pursuant to our qualifying contract under the Federal Supply Schedule or FSS, as well as open market sales to individual facilities within the government channels. While we have submitted a follow- on offer application for a new contract, there can be no assurance our application will be accepted which could adversely impact our business, results of operations, and financial condition. The majority of our 2023 sales were made pursuant to our qualifying contract under the Federal Supply Schedule or FSS, which was secured by us in December 2018, as well as open market sales to individual facilities within the government channels. The initial term of our FSS contract was scheduled to expire on January 15, 2024. On January 5, 2024, we obtained a modification to the initial contract, temporarily extending the term from January 15, 2024, to March 14, 2024, and subsequently extended to June 14, 2024. Although we continue to work with the appropriate government personnel to obtain a follow- on FSS contract, there can be no assurance that the VA / DoD will accept our follow- on application and replace our contract which may limit or eliminate our ability to sell certain gammaCore products into the government channel pursuant to our qualifying FSS contract or individual facilities that utilize our FSS contract number for open market purchases. The delay in contract replacement or loss of our FSS contract altogether could adversely affect our business, results of operations, and financial condition. In August 2023, we signed a non- exclusive distribution agreement with Lovell Government Services (Lovell) providing Lovell the right to list and distribute certain gammaCore products into the federal market. The gammaCore products offered through Lovell provide government customers with similar product configuration options to those currently sold through our existing FSS contract and open market sales made directly to individual VA / DoD facilities. Between November 2023 and January 2024, certain gammaCore products were added to the FSS, the VA / DoD' s Distribution and Pricing Agreement (DAPA), GSA Advantage, and Defense Logistics Agency' s ECAT system** procurement portals through the Lovell contract vehicles, enabling the purchase of gammaCore products within the government channel and throughout the federal markets, including, but not limited to, the VA / DoD. We expect a significant portion of our 2024 sales to continue in the government channel broadly pursuant to our FSS contract if extended and / or through our relationship with Lovell and its qualifying FSS, GSA, DAPA, ECAT contracts for which gammaCore has been added. There can be no assurance that government channel customers will adopt the new ordering process through Lovell and its qualifying FSS, GSA, DAPA, ECAT contracts, which could adversely affect our business, results of operations, and financial condition. We derive a material portion of our revenue from a limited number of customers, and the loss of one or more of these customers could adversely impact our business, results of operations, and financial condition. Our customer base is concentrated. During the years ended December 31, 2023 and 2022 ~~and 2021~~, revenue from ~~Department of Veteran Affairs and Department of Defense (~~VA / DoD ~~)~~ facilities pursuant to the terms and conditions of our qualifying contract under the FSS ~~Federal Supply Schedule~~ and open market sales represented 60. ~~8~~ 1 % and 59. ~~8~~ 3 % of our total revenue, respectively. In ~~2022~~ 2023 , ~~five~~ eight specific VA / DoD facilities represented approximately ~~52~~ 63 . 8 % of our revenue from this channel, and ~~one~~ two of those facilities accounted for more than 10 % individually. If we were to lose one or more of our significant customers, our revenue may ~~significantly decline~~ be adversely affected . The loss of one or more of our significant customers could adversely affect our business, results of operations, and financial condition. We expect ~~Because of these and~~ - an increasing portion of our 2024 sales will be made pursuant to the distribution agreement with Lovell and its contract vehicles, concentrating our customer base even further as revenue generated from the VA / DoD facilities pursuant to the terms and conditions of our qualifying contract under the FSS and open market sales is partially shifted to sales under our agreement with Lovell. Any delay in payments by our customers as well as any disagreement, disagreement or change in relationship status with Lovell or other customers could adversely affect ~~factors, it is likely that, in some future period,~~ our ~~operating~~ business, results ~~will not meet investor expectations or those~~ of ~~public market analysts. Any unanticipated change in revenues or operating~~ operations ~~results is likely to cause our stock price to fluctuate. New information may cause investors and analysts to revalue our business~~ , and financial condition ~~which could cause a decline in our stock price~~ . Failure to protect our information technology infrastructure against cyber- based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results. We rely on information technology and telephone networks and systems, including the internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, customer service, marketing, procurement and supply chain, manufacturing, and distribution. We also rely on information technology systems to support our proprietary data warehouse, which, among other things, maintains patient product serial numbers and allows for prescription refills at specialty pharmacies through RFID cards. In addition, we use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third parties, and the information technology systems of third parties may be susceptible to damage, disruptions, or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors, or catastrophic events. Despite the precautionary measures we and third parties have taken to prevent breakdowns in information technology and telephone systems, if these systems are breached or suffer severe damage, disruption, or shutdown, and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer, and we may be subject to related lawsuits. 23 We may engage in future acquisitions that increase our capital requirements, dilute our stockholders, cause us to incur debt, or assume contingent liabilities that subject us to other risks. We may evaluate various strategic transactions, including licensing or acquiring complementary therapies, products and technologies, or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation of operations and products, retention of key employees, diversion of our management' s attention, and uncertainties in our ability to maintain key business relationships of the acquired entity or entities. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses, and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. ~~22We~~ We may seek to grow our business through acquisitions or investments in new or complementary businesses, products, or technologies through the licensing of products or technologies from third parties. The failure to manage acquisitions, investments, licenses, or other strategic alliances, or the failure to integrate them with our existing business, could harm our business. Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, and technologies. Accordingly, from time to time, we may consider opportunities to acquire or make investments in businesses ~~,~~ or make investments in or license other technologies and products, that may enhance our capabilities, complement our current products, or expand the geographic or product breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses, and other alliances involve numerous risks, including: • difficulty assimilating or integrating acquired or licensed technologies, products, or business operations; • issues maintaining uniform standards, procedures, controls, and policies; • unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write- offs of intangible assets or goodwill; • diversion of management' s attention from our core business and disruption of ongoing operations; • adverse effects on existing business relationships with suppliers, distributors, and customers; • risks associated with entering new markets in which we have limited or no experience; • potential losses related to investments in other companies; • potential loss of key employees of the acquired business; and • increased legal and accounting compliance costs. We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms or at all, or whether we will be able to successfully integrate any acquired business, product, or technology into our business or retain any key personnel, suppliers, or distributors. To finance any acquisitions, investments, or strategic alliances, we may choose to issue shares of our common stock or other equity- linked securities as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments, or strategic alliances using our stock as consideration. If serious adverse events or other undesirable side effects are identified during the use of our **prescription** gammaCore therapy in clinical trials or IITs (collectively and unless the context requires otherwise, " clinical trials "), it may adversely affect our development of such product candidates. Undesirable side effects caused by our **prescription** gammaCore therapy could cause us or regulatory authorities to interrupt, delay, or halt nonclinical studies and future clinical trials or could make it more difficult for us to enroll patients in clinical trials and could, if injuries occur, result in product liability litigation. If serious adverse events or other undesirable side effects or unexpected characteristics of our **prescription** 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 **prescription** 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. **24** ~~23Commercialization -~~ -- **Commercialization** of our **prescription** gammaCore Sapphire therapy for additional conditions may require clinical trials, which are very expensive, take a long time to complete, and are difficult to design and implement and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies, clinical trials, or commercial success. The risk of failure for our **prescription** gammaCore therapy in additional treatment areas is high. It is difficult if not impossible to predict when or if any of our product candidates will receive regulatory clearance or approval in additional areas of indication. To obtain the requisite regulatory clearance or approvals to market and sell our **prescription** 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 **prescription** gammaCore therapy in cluster and migraine headaches do not ensure that later preclinical studies or clinical trials will demonstrate similar results in other therapeutic indications, and it should be noted that we did not achieve the primary endpoints in our pivotal trials for cluster and migraine headaches. There can be no assurance that the FDA and other regulatory authorities will be satisfied by data from clinical trials for other treatment indications, even where we believe such data to be compelling. Our **prescription** gammaCore therapy may fail to show the desired safety and efficacy traits in additional areas of indication in future clinical trials despite having progressed through preclinical and earlier stage clinical trials. Many companies in the pharmaceutical and medical device industries have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have, nonetheless, failed to obtain marketing clearance or approval of their products. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory clearance and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected. Any clinical trial we conduct in the United States may subject us to additional costs and detriments compared to a foreign clinical trial, which may negatively impact our financial condition and our business. Conducting any clinical trial within the United States may subject us to additional costs and drawbacks, which may negatively impact our financial condition and our business. The costs of a foreign clinical trial (or FCT) may be significantly lower than costs of an equivalent trial in the United States, as the materials and location costs of an FCT may be lower than a trial within the United States. Electing to run a clinical trial within the United States may impose significant added financial costs compared to a FCT. Among other factors, the faster recruitment of patients overseas and completion of trials in a FCT may represent considerable cost savings that we would forego in conducting clinical trials within the United States. These and other costs from conducting any clinical trial for our **prescription** gammaCore therapy instead of a FCT may negatively impact our financial condition and our business. In addition, a FCT may offer other non- financial benefits, such as a larger potential population of qualified patients to participate in clinical trials compared against the potential enrollee population in the United States where clinical trials may compete for a limited number of the same potential patients. These and other foregone benefits of a FCT may negatively impact our financial condition and our business. If we are unable to enroll patients in future clinical trials, our research and development efforts could be adversely affected. Identifying and qualifying patients to participate in future clinical trials for our **prescription** gammaCore therapy in additional areas of indications are critical to our success. Successful and timely completion of future clinical trials will require that we enroll a sufficient number of patients who remain in the study until conclusion. If we are unable to enroll a sufficient number of patients in our future clinical trials, our timelines for recruiting patients, conducting clinical trials, and obtaining regulatory clearance or approval of our **prescription** gammaCore therapy in additional areas of indication may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology, or termination of clinical trials altogether. ~~24We~~ **25 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 **prescription** gammaCore therapy will increase our costs, slow down our expansion into additional treatment indications and approval process, and delay or potentially jeopardize our ability to commence product sales and generate future revenue. We have recently reduced resources in research and development which may delay our receipt of regulatory approvals for additional indications. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory clearance or approval of our **prescription** 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 **prescription** gammaCore therapy in additional treatment indications. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, will enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement and completion of clinical trials may be delayed, suspended or terminated as a result of many factors, including: ~~25~~ **26** • the FDA or other regulators disagreeing as to the design, protocol or implementation of clinical trials; • the delay or refusal of regulators or institutional review boards (or IRBs) to authorize us to commence a clinical trial at a prospective trial site; • changes in regulatory requirements, policies and guidelines; • delays or failure to reach agreement on acceptable terms with prospective clinical research organizations (or CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delays in patient enrollment ~~, due to COVID- 19 or other factors,~~ and variability in the number and types of patients available for clinical trials; • the inability to enroll a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial; • having clinical sites deviate from the trial protocol or dropping out of a trial; • negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials, or to abandon projects that we expect to be promising; • safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks; • reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns; • regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including non- compliance with regulatory requirements or safety concerns, among others; • lower than anticipated retention rates of patients and volunteers in clinical trials; • our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial; • delays relating to adding new clinical trial sites; • difficulty in maintaining contact with patients after treatment, resulting in incomplete data; • delays in establishing the appropriate dosage levels; • the quality of the product candidate falling below acceptable standards; • the inability to manufacture sufficient quantities of our **prescription** gammaCore therapy to commence or complete clinical trials; and • exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials. Consistent with recent years, we continue not to invest in certain clinical trials in indications that are more exploratory in nature. We could also encounter delays if a clinical trial is suspended or terminated (or paused by us, as we have done with our PREMIUM II trial) by the IRBs or ethics committees of the institutions at which such trials are being conducted, by the data safety monitoring board for such trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA' s current Good Clinical Practice (or GCP) regulations, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations, or administrative actions, or lack of adequate funding to continue the clinical trial. ~~26In~~ **27 In** addition, we may encounter delays if the FDA, or other regulators, conclude that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site, or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and / or stock options in connection with such services. If these relationships and any related compensation to, or ownership interest by, the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA or other regulators conclude that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development. If we experience delays in the commencement or completion of any clinical trial of our product candidates, or if any of our future clinical trials are terminated, the commercial prospects of our **prescription** gammaCore therapy may be harmed, and our ability to generate revenue from sales may be delayed or materially diminished. We do not know whether any of our future preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence sales and generate associated revenue. Any of these occurrences may significantly harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial, suspension, or revocation of expanded regulatory clearance or approval of our product candidates. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. Even if our products are approved or cleared in the United States and obtain a CE Certificate of Conformity in the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval and clearance procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition, and prospects significantly. Our cost- control efforts might not assure profitability and may affect morale and make it difficult to retain employees or attract new ones. We have **from time to time** previously implemented reductions in force affecting a large portion of our workforce, redeployed resources across our organization, and taken other measures to reduce our operating expenses. These efforts do not assure profitability. Furthermore, no assurance can be given as to the need to implement additional cost reductions in the future. Cost savings may also be offset by future hiring or other costs incurred in pursuing strategic objectives. Reductions in force, strategic redeployment, and other cost- cutting measures could adversely affect morale in our organization and our reputation as an employer, which could lead to the loss of valued employees and could make it more difficult for us to hire new employees in the future, and the reduction of our headcount could adversely affect our operations and make it more difficult for us to pursue new opportunities and initiatives in the future. If we fail to properly manage our anticipated growth, our business could suffer. We have a relatively short history of operating as a commercial company. We intend to continue to grow our existing business and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems, and other resources. In particular, maintaining our sales force in the United States requires significant management, financial, and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our commercialization and development goals. In the future, we may experience difficulties with manufacturing, quality control, component supply, inventory, distribution, and shortages of qualified personnel, among other problems. These problems could result in delays in availability of our **prescription** gammaCore therapy **or general wellness products** and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate ~~our~~ revenue. Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train, or integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth, we will need to continue to improve our operational and management controls, reporting and information technology systems, and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy, and our operating results and business could suffer. ~~27If~~ **28 If** we fail to develop and retain an effective sales force, our business could suffer. In order to continue to market and sell our nVNS platform technology, we may in the future need to substantially expand our ~~direct~~ sales force. There is significant competition for such personnel. Once hired, the training process is lengthy because it requires significant education for new **sales personnel** ~~territory business managers~~ to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our territory business managers typically require" lead time" in the field to grow their network of accounts and achieve the productivity levels we expect them to reach. Furthermore, the use of our products often requires or benefits from direct support from us. If we are unable to attract, motivate, develop, and retain a sufficient number of qualified sales personnel, and if our **sales personnel** ~~territory business managers~~ do not achieve the productivity levels, we expect them to reach, our revenue will not grow at the rate we expect and, our financial performance will suffer. Also, to the extent we hire personnel from our competitors, we may have to wait until applicable non- competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories, and, in the past, we have been subject to, and may, in the future, be subject to, allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Any of these risks may adversely affect our business. We have limited history of commercializing **general** wellness products ~~withing~~ - **within** the United States or abroad. We have limited established relationships with stakeholders and experience in direct- to- consumer channels and limited relationships with third- party suppliers on whom we depend for the manufacture of our product components. If our competitors are better able to develop and market primary headache treatments that are safer, more effective, less costly, easier to use, or otherwise more attractive than our **prescription** gammaCore therapy, our business and business prospects will be adversely impacted. The pharmaceutical and medical device industries are highly competitive and subject to rapid innovation and change. Our success depends, in part, upon our ability to establish a competitive position in the cluster and migraine markets by securing broad market acceptance of our **prescription** gammaCore therapy. We believe that the primary competitive factors in the primary headache markets including those for CH and migraine headache are cost, demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects, and sales force experience and relationships. We face significant competition in the United States and internationally, which we believe will intensify over time. Many of the companies developing or marketing competing products enjoy several advantages over us, including: • more experienced and larger sales forces; • greater name recognition; • more established sales and marketing programs and distribution networks; • earlier regulatory clearance or approval; • long-established relationships with physicians and hospitals; • significant patent portfolios, including issued US and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third- party suppliers and distributors; • the ability to acquire and integrate our competitors and / or their technology; • demonstrated ability to develop product enhancements and new product offerings; • established history of product reliability, safety, and durability; • the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives; • greater financial and human resources for product development, sales, and marketing; and • greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products. Our competitors may develop and patent processes or products earlier than us, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products or processes more rapidly than us, or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. We also face fierce competition in recruiting and retaining qualified sales, scientific, and management personnel, establishing clinical trial sites, and enrolling patients in clinical studies. If our competitors are more successful than us in these matters, our business may be harmed. **29** ~~28Many~~ -- **Many** of our ~~primary headache~~ competitors are large, well- established companies with substantially greater resources than us and have a long history of competing in the migraine or **general** wellness markets. Many of our current and potential primary headache competitors are publicly traded, or are divisions of publicly traded, major pharmaceutical and medical device companies that have substantially greater financial, technical, sales and marketing resources than we do. We will face steep competition from Allergan plc, Amgen Inc., H. Lundbeck A / S, Novartis International AG, Teva Pharmaceutical Industries Ltd., Pfizer Inc., and Eli Lilly and Company, among other established and potential competitors that may be better capitalized and have a history of commercializing products around the world. Also, several neuromodulation devices are approved for the treatment and / or prevention of migraine, including Cefaly, Nerivo **, Savi Dual** , or any other neuromodulation devices that may be marketed for use in treating pain associated with primary headache. Cefaly has been granted an OTC clearance allowing it to be sold without a prescription, and the impact of this clearance on the competitive landscape remains to be seen. Given the size of the existing and potential market in the United States, we expect that, as we continue our commercial efforts in the United States, our current and future competitors, including any who may compete with us in the direct- to- consumer channel, will take aggressive action to protect their current share of the market. We will face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States. In addition, some physicians have a long-standing practice of using the headache products of our larger, more established competitors. Physicians who use our competitors' products for the treatment of migraine headache may be reluctant to try new products from a source with which they are less familiar. If these physicians do not try, and subsequently adopt, our product, then, our financial performance would be adversely affected. In the United Kingdom, three of the CGRP monoclonal antibody therapies have been recommended for use in the National Health Service by the National Institute Health and Care Excellence for the prevention of migraine. All of our current business with the National Health Service in the United Kingdom is for the prevention and treatment of cluster headache, and these recommendations may limit our ability to penetrate the NHS migraine market in the United Kingdom. Furthermore, a number of our competitors are currently conducting, or we anticipate will be conducting, clinical trials to demonstrate the results of their headache products. The results of these trials may be equivalent to, or potentially better than, the results of our clinical trials, which could have a material adverse effect on us. The completion of our competitors' clinical trials with respect to their headache products could negatively impact the perception of us or our **prescription** gammaCore therapy. In addition, perception by physicians, payors, or patients that a competitor' s product is superior to our **prescription** gammaCore therapy or offers comparable benefits at a lower cost or lower incidence of undesirable side effects as compared against our **prescription** gammaCore therapy, among other perception- driven outcomes in the market following competitors' completion of their clinical trials, could have a material adverse effect on us. Given our nascent entry into the diverse human performance and **general** wellness market, we expect that the barriers of entry and competitive effects may be significant factors impacting our success in the research and development, advertising, marketing, promotion, distribution, and sale of our general wellness products, Truvaga and TAC- STIM **branded products** , respectively. We expect to continue to perform, or engage with consultants to perform, where appropriate, extensive market research and other economic analysis to appropriately understand market participants' product offerings and contextualize various empirical and conjectural properties of market structure, including pricing patterns, competitive or anticompetitive tendencies, collaborative ventures and synergies, and cross- market product substitutions and other consumer behavior inferences, among other factors. To effectively compete with more established marker participants in the **general** wellness industry, we may need to expand our product offerings and distribution channels, which, in the interim, could increase our research and development costs and decrease our operating margins, thereby adversely impacting our business, financial condition, and results of operations. Some of the world' s largest technology companies that have not historically operated in the **general** wellness and / or medical device spaces, such as Alphabet Inc., Amazon. com, Inc., Apple Inc., Samsung Electronics Co., Ltd., and others have notably developed or may in the future develop products and technologies that may compete with our current or future products and technologies. Such companies have substantially greater capital, research and development, and sales resources than we have. Future research or investigative reports or publicity that is perceived as unfavorable or that question certain claims associated with or methods underlying our general wellness products could result in a decline in our revenues. Because of our final dependence on consumer perceptions, adverse publicity associated with illness or other undesirable effects resulting from the use of our products or similar products by competitors, whether or not accurate, could also damage customer confidence in our existing and any future general wellness products and result in a decline in revenues. Adverse publicity could arise even if the unfavorable effects associated with our general wellness products resulted from the user' s failure to use such products appropriately. **30** ~~29Traditional products used to treat CH and migraine have been available for decades, while our gammaCore therapy has only been commercially available in Europe for several years, and for approximately four years in the United States, and, as a result, we have a limited track record compared to our competitors. Traditional products used to treat CH and migraine have been commercially available for decades, while we only began commercializing our gammaCore therapy in Europe to treat CH and migraine several years ago and within the past four years in the United States. Because we have a limited commercial track record compared to our competitors, and our gammaCore therapy generally has been utilized by patients for less time than other headache therapies, physicians and patients may be slower to adopt or recommend our gammaCore therapy. In addition, while we believe our international commercial experience and our clinical trials support the safety and effectiveness of our gammaCore therapy for the acute treatment of eCH and prevention of CH and migraine headache, future studies or patient experience over a longer period of time may indicate that treatment with gammaCore is less attractive than treatment with competitive products, or that our gammaCore therapy causes unexpected or serious complications or other unforeseen negative effects. Such results would likely slow the adoption of our gammaCore therapy and significantly reduce our sales, which would harm our business and adversely affect our results of operations. Furthermore, if patients with traditional or other headache products were to experience unexpected or serious complications or other unforeseen effects, the market for our gammaCore therapy may be adversely affected, even if such effects are not directly attributable to our gammaCore therapy.~~ We may expend our limited resources to pursue a particular product candidate or disease and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus our research programs and product candidates on specific conditions. As a result, we may forego or delay **the** pursuit of opportunities with other product candidates or other diseases or conditions that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific conditions may not yield any commercially viable products. Our international operations subject us to certain operating and compliance risks, which could adversely impact our results of operations and financial condition. Sales of **prescription** gammaCore **therapy** outside of the United States represent a substantial portion of our net sales. In 2012, commercial operations began in the United Kingdom and Germany, and we now sell **our prescription** gammaCore ~~throughout~~ **therapy in** Europe from our UK based subsidiary and via ~~two~~ distribution partners ~~based in Belgium and Lithuania~~. Outside of Europe, we have a network of ~~8~~ distribution partners tasked with selling **our prescription** gammaCore **therapy** to patients in **select global markets** ~~Canada, Australia, New Zealand, United Arab Emirates, Bahrain, Oman, Saudi Arabia, Cyprus, China, Taiwan, Indonesia, Malaysia and Singapore~~. The sale and shipment of **our prescription** gammaCore **therapy** across international borders and the purchase of components from international sources subjects us to U. S. and foreign governmental trade and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non- compliance. Other laws and regulations that can significantly impact us include various anti- bribery laws, including the U. S. Foreign Corrupt Practices Act of 1977 (or FCPA), as amended, and export controls laws. The failure to comply with U. S. Foreign Corrupt Practices Act and similar worldwide anti- bribery laws in non- U. S. jurisdictions could materially adversely affect our business and result in civil and / or criminal sanctions. With regard to FCPA, the UK Bribery Act, and similar worldwide anti- bribery laws in non- U. S. jurisdictions, such laws generally prohibit companies and their intermediaries from making improper payments to non- U. S. government officials and, in some instances, other persons for the purpose of obtaining or retaining business. Because of the predominance of government- sponsored healthcare systems around the world, most of our customer relationships outside of the United States are or will be with governmental entities and are therefore potentially subject to such anti- bribery laws. Notably, global enforcement of anti- corruption and anti- bribery laws, which are typically interpreted broadly to prohibit generally companies, their employees, and their third- party intermediaries from authorizing, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector, has increased substantially in recent years, which has in part led to more frequent voluntary self- disclosures by companies, aggressive investigations and enforcement proceedings by U. S. and foreign governmental agencies, and assessment of significant fines and penalties against companies and individuals in various cases. **31** ~~30Thus~~ -- **Thus**, our international operations create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors because these parties are not always subject to our direct oversight and control. As we increase our international sales and direct greater levels of business and sales toward the public sector, we may engage with business partners and third- party intermediaries to market our products and to obtain necessary permits, licenses, and other regulatory approvals. In addition, we or our third- party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state- owned or affiliated entities. ~~[~~It is therefore our policy to implement safeguards to educate our employees and agents on these legal requirements and discourage improper practices. ~~]~~However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, contractors or consultants, partners, sales agents, or distributors may engage in conduct for which we might be held ultimately responsible as principal. Specifically, we can be held liable for the corrupt or other illegal activities of these third- party intermediaries, our employees, representatives, contractors or consultants, partners, and sales agents, or distributors, even if we do not explicitly authorize such activities. Detecting, investigating, and resolving actual or alleged violations of anti- corruption and other laws can require a significant diversion of time, resources, and attention from our business. In addition, government agencies may seek to hold us liable for successor liability for anti- corruption law violations committed by any companies in which we invest or that we acquire in the future. Any alleged or actual violations of these regulations may subject us to expensive government scrutiny, severe criminal or civil sanctions and other liabilities, including exclusion from government contracting, reputational harm, adverse media coverage, and such alleged or actual violations could disrupt our business and result in a material adverse effect on our business, financial condition, and results of operations. As we expand contract relations internationally, our risks under these laws may increase. In general, any failure to comply with the applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil, and administrative penalties, including imprisonment of individuals, fines, and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. The U. S. administration of President Biden may support potential trade proposals (including import tariffs and other tariffs on China), modifications to international trade policy, and other changes that may affect U. S. trade relations with other countries. We source a significant amount of the components used in gammaCore from Chinese sources, so any tariffs or other trade restrictions impacting the import of these components from China could have a material adverse impact on us. ~~In addition, the ongoing COVID- 19 pandemic has caused many countries to restrict certain manufacturing activities and has severely disrupted the movement of certain goods. As a result, our distributors, agents, and suppliers may not have the materials, capacity, or capability to operate as our business ordinarily requires.~~ Additionally, our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include: • difficulties in enforcing our intellectual property rights and in defending against third- party threats and intellectual property enforcement actions against us, our distributors, or any of our third- party suppliers; • reduced or varied protection for intellectual property rights in some countries; • pricing pressure that we may experience internationally; • a shortage of high- quality salespeople and distributors; • third- party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs, or that may necessitate the reduction of the selling prices of gammaCore; • competitive disadvantage to firms with established business and customer relationships; • foreign currency exchange rate fluctuations; • the imposition of additional U. S. and foreign governmental controls or regulations; • economic instability; • changes in duties and tariffs, license obligations, and other non- tariff barriers to trade; • the imposition of restrictions on the activities of foreign agents, representatives, and distributors; • scrutiny of foreign tax authorities, which could result in significant fines, penalties, and additional taxes being imposed on us; ~~31~~ **32** • laws and business practices favoring local companies; • longer payment cycles; • difficulties in maintaining consistency with our internal guidelines; • difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • the imposition of costly and lengthy new export licensing requirements; • the imposition of U. S. or international sanctions against a country, company, person, or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person, or entity; • the imposition of new trade restrictions; and • disruptions caused by Brexit. If we experience any of these risks, our sales in non- U. S. jurisdictions may be harmed, and our results of operations would suffer. Our results may be impacted by changes in foreign currency exchange rates. We have international operations and, as a result, an increase in the value of the U. S. dollar relative to foreign currencies could require us to reduce our selling price or risk making our products less competitive in international markets. Our general costs of doing business could increase. Also, if our international sales increase, we may enter into a greater number of transactions denominated in non- U. S. dollars, which could expose us to increased foreign currency risks, including currency fluctuations and exchange rate risks and indirect effects from net capital flows related risks, such as capital flight and any cross- border capital controls. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful, and our business could be harmed. We may not be able to establish or strengthen our brands. We believe that establishing and strengthening the electroCore, gammaCore, Truvaga, and TAC- STIM brands are critical to achieving widespread acceptance of our nVNS platform technology. We believe that brand awareness considerations are particularly significant in light of the highly competitive nature of the burgeoning markets for headache therapies and **general** wellness products. Promoting and positioning our brand will depend largely on the success of our marketing efforts, our direct- to- consumer initiatives, and our ability to provide physicians, patients, and consumers with a reliable product. Given the established nature of our competitors, our relative lack of commercialization in the United States and our lack of experience in the direct- to- consumer channels, it is likely that our future marketing efforts will require us to incur significant additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brands. If we fail to successfully promote, expand, and maintain our brands, or if we incur substantial expenses in an unsuccessful attempt to promote, expand, and maintain our brands, nVNS platform technology may not be accepted by physicians and consumers, which would adversely affect our business, results of operations, and financial condition. ~~32We~~ **33 We** may face product liability claims that could result in costly litigation and significant liabilities. Manufacturing and marketing of our nVNS platform technology and clinical testing of our **prescription** gammaCore therapy may expose us to individual product liability claims, class action lawsuits or actions, and other individual or mass tort claims. Regardless of the merits or eventual outcome, liability claims may result in any of the following: • decreased demand for our products or products that we may develop in the future; • decline in price charged for our products; • loss of revenue; • injury to our reputation; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants; • product recalls or withdrawals; • labeling, packaging, marketing or promotional modifications or restrictions; • exhaustion of any available insurance and our capital resources; • the inability to commercialize our existing or future products; and • a decline in our stock price. Although we have, and intend to maintain, liability insurance, the insurers may deny our claims, and coverage limits of our insurance policies may not be adequate. Specifically, we may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations, or that are not covered by the terms and conditions of our insurance policies, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. These risks are particularly heightened in the event any product recalls take place as a result of any product design defect or defect in product warnings or labeling. One or more successful claims brought against us may have a material adverse effect on our business and results of operations. Even successful defense would require significant financial and management resources. **34** ~~33Our~~ -- **Our** operating results and profitability may be adversely affected by increases in reserves for product returns, doubtful accounts receivable, and inventory. Our net sales and profitability are affected by changes in reserves to account for product returns, doubtful accounts receivable, and inventory. Significant management judgment must be used, and estimates must be made in relation to establishing the foregoing reserves, and any increase thereto could adversely affect our reported financial results by reducing our net revenues and / or profitability for the given reporting period. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, or if third- party payors were to deny claims, additional provisions for doubtful accounts may be required. We permit the return of damaged or defective products and accept limited amounts of product returns in certain instances. While such returns are expected to be nominal and within management' s expectations and the provisions established, future return rates may increase more than anticipated. We have established a reserve in our financial statements for product returns, and we will continue to analyze our returns to determine the adequacy of the reserve. Any significant increase in damaged or defective products or expected returns could have a material adverse effect on our operating results for the period or periods in which such returns materialize. Additionally, damaged or defective products could (i) adversely affect our reputation and our end customers' willingness to buy products from us, (ii) adversely affect market acceptance or perception of our products, (iii) increase our service costs, (iv) cause us to lose significant end- customers, ~~and~~ (v **) result in punitive actions from regulatory bodies and (vi**) subject us to liability for damages and divert our resources from other tasks, any of which could materially and adversely affect our business, asset valuations, results of operations, and financial condition. If we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely affected while we attract other highly qualified personnel. Our future success depends, in part, on our ability to continue to retain our executive officers and other key employees and recruit and hire new employees. All of our executive officers and other employees are at- will employees and therefore may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel likely would involve significant time and costs, may significantly delay or prevent the achievement of our business objectives, and may harm our business ~~. In particular, our potential revenue in the United Kingdom is dependent on a small number of certain key UK personnel. In addition, many of our employees have unvested equity awards in a substantial amount of stock or stock options that have lost significant value since they were granted. Our employees may be more likely to leave us if the shares they own or the shares underlying unvested options have significantly depreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly above the market price of our common stock. Further, our employees' ability to exercise those options and sell their stock in a public market may result in a higher- than- normal turnover rate. In addition, our financial condition may preclude us from giving additional cash compensation to militate against this risk~~ . Many executive officers and employees in the pharmaceutical and medical device industries are subject to strict non- compete or confidentiality agreements with their employers, which may include our main competitors. In addition, some of our existing and future employees are or may be subject to confidentiality agreements with previous employers. Our competitors may allege breaches of, and seek to enforce, such non- compete agreements or initiate litigation based on such confidentiality agreements. This litigation, whether or not meritorious, may impede our ability to attract or use executive officers and other key employees who have been employed by our competitors and may result in intellectual property claims against us. It is likely that we will experience similar aggressive lawsuit tactics by our competitors while they seek to protect their market position, particularly as we prepare to expand in new or existing markets. **If we are unable to retain the independent consultants in our sales force or attract independent consultants, our sales efforts may be adversely impacted. The independent consultants in our sales force may terminate their services at any time. We have experienced and are likely to continue to experience turnover among independent consultants. The departure for any reason of any of our independent consultants could have a negative impact on our sales and operating results. While we take steps to help train, motivate, and retain independent consultants, we cannot accurately predict the number or sales productivity of our independent consultants. 35 Our operating results will be harmed if we and the independent consultants in our sales force do not generate sufficient interest in our products to retain such consultants and attract new consultants. The number and sales productivity of the consultants could be harmed by several factors, including: • any adverse publicity regarding us, our products, our distribution channel, or our competitors; • non- compliance by our independent consultants with applicable legal requirements or our policies and procedures; • lack of interest in existing or new products or their failure to achieve desired sales results; • lack of a compelling business opportunity sufficient to generate the interest and commitment of new independent consultants; • any changes we might make to our independent consultant sales compensation plan; • any negative public perception of our company or our products; • any negative public perception of our independent consultants; • our actions to enforce our policies and procedures; • any efforts to sell our products through competitive channels; • any regulatory actions or charges against us or others in our industry; and • general economic and business conditions. We may be held responsible for certain taxes or assessments and other obligations relating to the activities of our independent consultants, which could harm our financial condition and operating results. Our independent consultants are subject to taxation, and in some instances, legislation or governmental agencies impose an obligation on us to collect or withhold taxes, such as value added taxes or income taxes, and to maintain appropriate records. In the event that local laws and regulations or the interpretation of local laws and regulations change to require us to treat our independent consultants as employees, or that our independent consultants are deemed by local regulatory authorities in one or more of the jurisdictions in which we operate to be our employees rather than independent contractors under existing laws and interpretations, or our independent consultants are deemed to be conducting business in countries outside of the country in which they are authorized to do business, we may be held responsible for social security, income, and other related taxes in those jurisdictions, plus any related assessments and penalties, which could harm our financial condition and operating results. If our independent consultants were deemed to be employees rather than**

independent contractors, we may be obligated to pay certain employee benefits, such as workers compensation and unemployment insurance. Further, if our independent consultants are misclassified as employees, we would also face the threat of increased vicarious liability for their actions. Our future success depends on our leadership development and succession planning. Effective succession planning is important to our long- term success. Failure to ensure effective transfer of knowledge and smooth transitions involving key employees and senior executives could hinder our strategic planning and execution. Our ability to execute our business strategies, ensure a cohesive management team, and attract and retain key executives may be adversely affected by the uncertainty that could be associated with the transition to new senior leadership. **36** ~~34Our~~ -- **Our** employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, independent contractor ~~influences~~ **influencers** , other content creators, consultants, commercial collaborators, principal investigators, CROs, and vendors may engage in fraudulent conduct or other illegal activity. Possible misconduct by these parties, including intentional, reckless, or negligent conduct or otherwise unauthorized activities, that violates the (1) laws and regulations of the FDA, FTC, and other similar regulatory authorities, including those laws requiring the reporting of true, complete, and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud, and abuse and other healthcare laws and regulations in the United States and abroad, such as the General Data Protection Regulation in the European Union, and (4) laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, advertising and marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, advertising, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Misconduct by the foregoing parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, and the curtailment or restructuring of our operations. Regarding advertising risk in the United States in particular, the FTC and states' attorneys general are primarily responsible for enforcing the consumer protection laws by, among other things, investigating and initiating enforcement actions against business practices they deem to be deceptive or fraudulent under applicable laws. We are thus subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products or marketing or advertising efforts. In connection with the marketing or advertisement of our products, we could be the target of claims relating to false, misleading, deceptive or otherwise noncompliant advertising or marketing practices, including under the auspices of the FTC and state consumer protection statutes. If we rely on third parties to provide any marketing and advertising of our products, we could be liable for, or face reputational harm as a result of, their marketing practices if, for example, they fail to comply with applicable statutory and regulatory requirements. We cannot ensure that all marketing materials currently used for our products comply with applicable laws, rules, and regulations, including bans on false and misleading product related claims. Any failure to comply with these restrictions could subject us to assertions of claims of false advertising and misrepresentation, which potentially bring forth significant financial penalties, costly mandatory product recalls, or relabeling requirements, any of which could have a material adverse effect on our results of operations and financial condition. If we are found to have breached any consumer protection, advertising, unfair competition or other laws or regulations, we may be subject to enforcement actions that generally require us to amend our marketing and business practices in a manner that may negatively impact us. This could also result in litigation, fines, penalties, and adverse publicity that could cause reputational harm and loss of customer trust, which could have a material adverse effect on our business, financial condition and results of operations. ~~35~~ **37** The increasing use of social media could give rise to liability. Social media, including Instagram, Snapchat, TikTok, Facebook, **LinkedIn and X, the social media platform formerly known as** and Twitter, are increasingly being used to communicate about our products, clinical development programs, and, at present, the conditions our **prescription** gammaCore therapy is being developed to treat **and potential general wellness improvements** . We are engaging in what we believe is appropriate social media usage in connection with our commercialization efforts for indications for which our therapy has been approved **and for potential general wellness improvements** . We intend to do the same for any future indications or products, if approved. Social media practices in the medical device and **general** wellness industries continue to evolve, and regulations and regulatory guidance relating to such practices are mutable and unclear at times. This evolution creates uncertainty and elevated risk of non- compliance with regulations applicable to our business, which can result in potential regulatory actions against us or potential litigation related to " off- label " marketing or other prohibited activities. For example, for our clinical- stage candidates, patients and consumers may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event. When such disclosures occur, there is a risk that study enrollment may be adversely impacted, or we fail to monitor and comply with applicable adverse event reporting obligations, or that we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any online platform, including a blog on the Internet, or a post on a website, that can be distributed rapidly and could negatively harm our reputation. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our company policies or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial participants, customers, consumers, and others. Our efforts to promote our products via marketing and social media initiatives may subject us in the future to additional scrutiny of our practices of effective communication of risk information, benefits, or claims, by the FDA, FTC, or both. If any of the aforesaid events were to occur, or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or cause other injury to our business and stockholders. Risks Related to ~~COVID~~ **our Dependence on Third Parties We have signed a distribution agreement with Lovell to sell certain gammaCore products throughout the government channel through Lovell' s contract vehicles, and we may therefore be dependent on Lovell. Between November 2023 and January 2024, certain gammaCore products were added to the FSS, the DAPA, GSA Advantage, and Defense Logistics Agency' s ECAT system procurement portals through the Lovell contract vehicles. We expect an increasing portion of our 2024 sales will be made pursuant to the distribution agreement with Lovell and its contract vehicles. Furthermore, we have submitted a follow** - ~~19The ongoing coronavirus pandemic could have a significant negative impact~~ on **offer application to replace** ~~our business, revenues, financial condition, results of operations, and cash flow, and other epidemics or~~ **our existing FSS contract which is set** ~~outbreaks of infectious diseases may have a similar impact. The ongoing coronavirus pandemic has impacted, and may continue~~ to ~~impact~~ **expire on June 14** , **2024. If** our ~~headquarters~~ **follow- on offer application for renewal is not accepted** , ~~manufacturing, and warehousing and ecommerce facilities,~~ **our sales within the government channel will be largely dependent on the Lovell contract vehicles. Any delay in payments by our customers** as well as ~~those of~~ **any disagreement disruption** ~~our~~ - **or change in the status of the relationship with Lovell or other customers or Lovell' s ability to execute orders could negatively impact our business, results of operations, and financial condition. We are offering products to government customers through two different contracting vehicles, which may cause confusion for purchasing agents and result in frustration by customers. Beginning in November 2023, gammaCore products have been available to government customers directly through our existing FSS contract, via open market purchases for individual VA / DoD facilities, and through Lovell. Offering different products at different price points may cause confusion for purchasing agents, which may result in loss or delay of sales to customers. Furthermore, we have submitted a follow- on offer application to replace our existing FSS contract which is set to expire on June 14, 2024. The replacement contract, if granted, will have a different contract number than what was previously used for purchases by customers. Any frustration or confusion by customers associated with gammaCore offerings through multiple procurement contracts or contract identifiers may adversely impact our business, results of operations, and financial condition. We have signed a distribution agreement with Joerns Healthcare (" Joerns ") to sell certain gammaCore products throughout certain managed healthcare systems through the Joerns contract vehicles which puts a significant dependence on Joerns. In October 2022, certain gammaCore products were added to the Joerns DME catalog for distribution throughout certain managed care healthcare systems. We expect a portion of our 2024 sales will be made pursuant to the distribution agreement with Joerns and their contract vehicles. Any change in the status of the relationship or Joerns' ability to execute orders could negatively impact our business. 38 Our new app- enabled consumer product relies on** third- party **vendor for application development and management which puts a significant dependency on the third- party vendor. We intend to launch our next generation app- enabled consumer product under the Truvaga brand in 2024. The customer- facing application was developed by a third- party vendor on their proprietary platform. We depend on our technology** vendors ~~, including through the effects~~ **to manage " up- time "** of ~~facility closures, employee furloughs, reductions in operating hours, staggered shifts and other~~ -- **the** ~~social distancing efforts~~ **front- end customer- facing application** , ~~labor shortages~~ **device connectivity** , ~~decreased productivity,~~ and ~~unavailability~~ **back- end administration portals. Any failure on the part** of ~~materials or~~ **our** ~~components~~ **third- party application developer, or in our ability to transition third- party services effectively, could result in lost sales and harm our business** . The **third** ~~ongoing coronavirus pandemic may also impact our ability to sell our product, ship our product on a timely basis, and may increase our costs. The spread of coronavirus caused us to modify certain of our business practices (including social distancing practices, requiring non~~ - **party application developer information technology systems** ~~essential production related team members to work remotely where possible~~ , **some of which are managed** ~~restricting business travel, cancelling certain events, and limiting visitor access to our facilities), and we may relax, extend, modify, or take further actions that may be required~~ by ~~government authorities or that we determine are necessary or advisable. Work- from- home and other measures introduce additional operational risks, including cybersecurity risks, and have affected the way we conduct our business, which could have an adverse effect on our operations. There is no certainty that such measures will be sufficient to mitigate the risks posed by the virus, and illness and workforce disruptions could lead to unavailability of key personnel and harm our ability to perform critical functions. In addition, work- from- home and related business practice modifications present significant challenges to maintaining our corporate culture, including employee engagement and productivity, both during the ongoing pandemic crisis and as we make additional adjustments in the eventual transition from it. Implementing new business practices to protect employees, vendors, and other parties with whom we interact may result in increased costs. Furthermore, even if we follow what we believe to be best practices, there can be no assurance that our measures will prevent the transmission of COVID- 19 between employees. Any incidents of actual or perceived transmission may expose us to liability claims, adversely~~

~~impact employee productivity and morale, and result in negative publicity and reputational harm. Additionally, our sales and marketing efforts are, and may from time to time be, adversely affected by protocols for screening and restricting outside visitors and vendors that have been adopted by the Department of Veterans Affairs, commercial prescribers, and other~~ third parties **,** ~~. Officially imposed quarantines~~ and **the information technology systems of third** ~~self- quarantines could also interfere with patients -~~ - **parties** ~~' ability~~ **may be susceptible** to **damage, disruptions,** ~~see a health care provider and obtain our -~~ - **or shutdowns due** ~~gammaCore therapy. 36 The degree~~ to ~~which coronavirus impacts~~ **computer viruses, attacks by computer hackers, failures during the process of upgrading** ~~our -~~ **or** ~~results will continue~~ **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 ~~depend on future developments that~~ **prevent breakdowns in information technology systems, if these systems** are **breached** ~~highly uncertain and cannot be predicted, including, without limitation, the timing, extent, trajectory, and duration of the pandemic; the development, rollout, and availability of effective treatments and vaccines; the imposition of protective public safety measures; vaccine mandates; the transmissibility and effects of new coronavirus variants; and how quickly and to what extent normal economic and operating conditions resume, if at all. These uncertainties may result in delays or modifications to our -~~ - **or** ~~plans~~ **suffer severe damage** , **disruption,** ~~initiatives and results. For -~~ - **or shutdown** ~~the reasons set forth above and any other reasons that may come to light as the coronavirus pandemic continues and associated protective or preventative measures transpire~~ , **and** we are unable to ~~reasonably estimate coronavirus' impact to~~ **effectively resolve the issues in a timely manner,** our business ~~, revenues, financial condition,~~ and **operating** results ~~of operations~~ **may suffer** . We ~~are similarly unable to predict the degree to which the ongoing pandemic impacts our customers, suppliers, vendors, and other partners, and their financial conditions, but a material effect on any of these parties could also adversely affect us. The impact of coronavirus could also exacerbate other risks discussed below, which could in turn have a material adverse effect on us. Developments related to coronavirus have been rapidly changing, and additional impacts and risks may arise that we are not aware of or able to appropriately respond to currently. More generally, in the future, our business, financial results, and financial condition may be negatively impacted by the effects of other disease outbreaks, epidemics, pandemics, or similar widespread public health concerns. Risk Related to our Dependence on Third PartiesWe~~ have relied upon primary, secondary, and sole source third- party suppliers located in China and elsewhere for components and packaging of our gammaCore products, which suppliers have paused delivery at our request, thereby making us vulnerable to supply shortages, price fluctuations, and an inability to reactivate supply chains **,** if necessary, all of which could harm our business. A number of the critical components used in gammaCore are supplied to us from either a primary, or secondary manufacturer, and multiple suppliers of high- demand consumer electronic components, and in certain cases sole- source, suppliers. Our manufacturers and suppliers may encounter problems during manufacturing for a variety of reasons ~~, including, for example, disruptions caused by COVID- 19~~ , failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third- party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our ability to supply gammaCore commercially depends, in part, on our ability to obtain a supply of these components that has been manufactured in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We have not entered into manufacturing, supply or quality agreements with suppliers of consumer electronic components, some of which supply components critical to our products. Although we believe that long- term agreements with these suppliers are not necessary as all the components in our products are either high- volume, non- custom commodity components or are readily available from multiple vendors, there can be no assurance that our multiple- source or sole- source suppliers will be able to meet our demand for their products and services, either because of the informal nature of our arrangements with those suppliers, or our limited experience with those suppliers, due to our relative importance as a customer to those suppliers, or due to supply chain disruptions that may arise such as those relating to ~~COVID- 19 and the coronavirus pandemic,~~ the armed conflict between Russia and Ukraine, trade sanctions, and similar events. It may be difficult for us to assess the ability of our suppliers to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers. Establishing additional or replacement suppliers for the components or processes used in gammaCore, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such **a** 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. ~~37In Europe~~ **39 We have limited experience with the supply chain of the new product we intend to launch, our next generation app- enabled consumer wellness product under the brand Truvaga, and are dependent on third parties for related software development. Many of the critical components that will be used in our next generation app- enabled consumer wellness product that we plan to launch under the brand name Truvaga are supplied to us from either a primary, or secondary manufacturer, as well as multiple suppliers of high- demand consumer electronic components, certain of whom are sole- source suppliers. We also have limited experience in selling an app- enabled consumer wellness product, and therefore we may be unable to reliably forecast the demand and inventory requirements for this type of product, which could directly or indirectly have**

an adverse effect on our business, results of operations and financial condition. In addition, we rely entirely on third-party software developers for the design and development of the software for this next generation product. If our third-party suppliers fail to deliver the required commercial quantities of materials, or our software developers fail to deliver or the level and quality of services, we require, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or developers capable of production or development at a substantially equivalent cost in substantially equivalent volumes and quality and on a timely basis, the continued commercialization of this product would be impeded, delayed, limited, or prevented, which could have an adverse effect on our business, results of operations, financial condition and prospects. Outside the United States , we rely on a single third- party distributor to effectively distribute the majority of our products. We depend in part on a single third- party distributor for the warehousing and shipment of our products in certain territories in ~~Europe~~ **outside the United States** . We depend on this distributor' s efforts; however, we are unable to control its efforts completely. This distributor typically performs the same services for a variety of other non- competing products that may limit the resources it dedicates to our **prescription** gammaCore therapy. If our distributor fails to effectively distribute gammaCore in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third- party distributors and training them in our technology and product offerings require significant time and resources. To develop and expand our distribution, we must continue to scale and improve our processes and procedures that support our distributors. In addition, our ability to recruit distributors and their effectiveness may be adversely affected by the armed conflict between Ukraine and Russia. Furthermore, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to maintain positive relationships with our distributor, fail to develop new relationships with other distributors (including in new markets), fail to manage, train, or incentivize our existing distributor effectively, or fail to strike agreements with attractive terms, or if our distributor is not successful in its businesses, our revenue may decrease, and our operating results, reputation, and business may be harmed. Our status as a **supplier to the** federal ~~contractor~~ **government** subjects us to a wide variety of regulatory compliance, pricing, and contract- based requirements. Failure to comply with these requirements could adversely impact our ability to obtain future federal contracts, which could negatively impact us and our business. We expect that a ~~majority~~ **portion** of our ~~2023~~ **2024** U. S. sales of gammaCore will be made pursuant to ~~our~~ qualifying ~~contract on the~~ FSS **, GSA, DAPA, and ECAT contracts,** and open market sales to individual VA facilities. Our status as a contractor on FSS means that we are obligated to comply with a variety of federal procurement laws, regulations, and contract terms that require commercial price disclosures, commercial- to- federal price indexing, and compliance with various federal programs. Furthermore, as a federal contractor, we are also subject to contractual remedies and potential administrative, civil, and criminal damages and penalties for non- compliance with contract terms, over billing, or misconduct. In addition to the above considerations, we have reason to believe that our prospective sales of human performance and general wellness products to the U. S. Armed Forces could involve various significant compliance requirements as regards applicable laws and regulations and certain contract law covenants and conditions that collectively regulate our affairs in the ordinary course of business as a result of our status as a federal contractor. The ~~recent Biden administration' s executive order requiring all on- site and remote federal employees, contractors, and sub- contractors to be vaccinated against COVID- 19 or receive an approved medical or religious exemption by December 8, 2021 may apply to us because of our Federal Supply Schedule Medical Equipment and Supply contract. Failure to comply with the executive order could lead to loss of the contract, which could have a material adverse effect on our business, revenues, financial condition, and result of operations. In light of the executive order, we implemented a mandatory COVID- 19 vaccination policy for all employees subject to religious and medical exemptions. There are, however, ongoing challenges in the federal courts regarding the validity of the executive order, which could lead to future changes to our own policies depending on the outcome of those cases. For now, the~~ cost of maintaining compliance with these requirements could adversely impact us and our business, and complying with these requirements could divert managerial and financial resources. Additionally, failure to comply could result in us being excluded from the opportunity to renew existing federal contracts or to bid on federal future contracts for a period of time lasting up to several years. Our ~~qualifying contract on the FSS is scheduled to expire on January 15, 2024. We intend to request an extension of the FSS from the United States Department of Veterans Affair, but there is no assurance the FSS contract will be renewed, if at all on terms favorable to us. Any of these contingencies could have a material adverse effect on our business, financial condition, and results of operations. Our~~ potential revenue in the United Kingdom is substantially dependent on government funding arrangements, and changes in governmental policy for such arrangements could cause material harm to our business. Effective April 1, 2021, gammaCore Sapphire was included in a new long- term reimbursement policy. The MTFM policy supports the use of NICE- approved, clinically effective and cost- saving medical devices, diagnostics, and digital technologies that will improve patient health. In December 2019, NICE published a Medical Technology Guidance document recommending the use of gammaCore for CH within the NHS. In ~~2023~~ **2024** , we expect NICE to review the guidance document, and any changes in recommendation or pricing may adversely impact our ability to work with NHS England on the MTFM program, which could have an adverse impact on our business in the United Kingdom. ~~38We~~ **40 We** rely on third parties to conduct and support clinical trials and investigator- initiated trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials. We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators to perform this function. Currently, we have a number of ongoing IITs. We frequently review both proposals for new trials and the performance of ongoing trials, and our reviews may result in changes to our future obligations. Our reliance on third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. Furthermore, some of the sites for our IIT' s are outside the United States. The performance of these sites may be adversely affected by various issues, including less advanced medical infrastructure, lack of familiarity with conducting clinical trials in accordance with U. S. standards, insufficient training of personnel, communication difficulties or change in local regulations. We remain responsible for ensuring that clinical trials are conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with GCP for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, including our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory clearance or approval for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products. Additionally, patient enrollment is affected by many factors beyond our control and the control of the third parties upon whom we rely to conduct IITs. As a result, we cannot predict how successful our IITs will be at enrolling patients. In particular, enrollment in our IITs for nVNS stimulation in COVID- 19 patients in the United States has been slower than expected. We also may rely on other third parties to store and distribute supplies for clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory clearance or approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenues. If we do not successfully enter into future collaborations for the development, regulatory clearance, and commercialization of our **prescription** 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 **prescription** 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 **prescription** 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 **prescription** gammaCore therapy are subject to numerous risks, which may include the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration; • collaborators may not pursue development, regulatory clearance, and commercialization of our product candidates, or may elect not to continue or renew development, regulatory clearance, or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; • a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution; ~~39~~ **41** • collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; • disputes may arise between us and a collaborator that cause the delay or termination of the research, development, or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and • collaborators may own or co- own intellectual property covering our products that result from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property. Any termination or disruption of any future collaboration could result in delayed development of product candidates, increased cost to develop product candidates, or termination of development of a product candidate. If we are not able to establish or maintain collaborations, we may have to alter some of our future development, regulatory clearance, and commercialization plans. Our product development programs, regulatory clearance, and potential commercialization of our nVNS platform technology will require substantial additional capital to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and medical device or consumer electronics companies for the future development, regulatory clearance, and potential commercialization of those product candidates. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in- license, or use these proprietary rights. We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator' s evaluation of a number of factors. We, or third- party manufacturers on whom we rely, may be unable to successfully sustain and to further scale- up manufacturing of our nVNS technology platform or its component parts in sufficient quality and quantity, which would delay or prevent us from developing and commercializing any approved products. In order to commercialize products, we, or our manufacturers, will need to manufacture products in large quantities. There are technical challenges to increasing manufacturing capacity, including equipment design, automation, validation and installation, contractor issues and delays, licensing and permitting delays or rejections, materials procurement, manufacturing site expansion, problems with production yields, and quality control and assurance. Continuing to develop or enhance commercial- scale manufacturing facilities could require the investment of substantial additional funds and the hiring and retention of additional management, quality assurance, quality control, and technical personnel who have the necessary manufacturing experience. ~~40~~ **42** The scaling of manufacturing capacity is subject to numerous risks and uncertainties and may lead to variability in product quality or reliability and increased construction timelines and resources required to design, install, and maintain manufacturing equipment, among others, all of which can lead to unexpected delays in manufacturing output. In addition, any changes to manufacturing processes may trigger the need for submissions or notifications to, and in some cases advance approval from, the FDA or other regulatory authorities because of the potential impact of changes on previously cleared, approved, and / or authorized devices. Our facilities are subject to inspections by the FDA and corresponding state **and international** agencies on an ongoing basis, and thus, we must comply with Good Manufacturing Practices, which generally require us to maintain compliant processes, controls, and record keeping, and to comply with FDA Quality System Regulations (or QSR), and applicable state- law requirements. We may be unable to adequately maintain, develop, and expand our manufacturing process and operations or maintain compliance with FDA and state agency requirements, and manufacturing issues could impact our cleared and approved products. If we are unable to manufacture a sufficient supply of our current products or any future products for which we may receive approval or clearance, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand, contractual obligations, and our business will suffer. In light of the above considerations, we, or our manufacturers, may be unable to successfully sustain, or increase manufacturing capacity in a timely or cost- effective manner, or at all. In addition, quality issues may arise during further scale- up activities. If we, or any of our manufacturers, are unable to successfully sustain, or further scale- up manufacturing in sufficient quality and quantity, the development, testing, and clinical trials, if appropriate, of our nVNS technology platform may be delayed or infeasible, and regulatory clearance, approval, or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third- party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our **prescription** gammaCore therapy successfully. We are required to maintain high levels of inventory due to lead times with single- source consumer electronic components vendors, which could consume a significant amount of our resources, reduce our cash flows, and lead to inventory impairment charges. Our nVNS technology platform consists of a substantial number of individual components. In order to market and sell effectively, we often must maintain high levels of inventory of the product and its components. The manufacturing process requires lengthy lead times during which electronic components of our nVNS technology platform may become obsolete, and we may over- or under- estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third- party manufacturers exposes us to greater lead times, increasing our risk of adverse financial impact of inventory obsolescence comparatively. In addition, as of December 31, ~~2022~~ **2023** , we had approximately $ ~~4.~~ 2 **. 8** million of inventory ~~. Our inventory significantly exceeds current demand for the nVNS technology platform, which also could result in an increased risk of adverse financial impact from inventory obsolescence~~ . There are ~~, however,~~ risks that growth in our business, including our recently launched non- prescription, human performance and **general** wellness offerings, may result in demand that could outstrip our current inventory, in which case we would be subject to various supply chain, manufacturing, and operational risks. If not mitigated fully, this could negatively impact our ability to commercialize our products and have a material adverse effect on our brands, revenues, expenses, results of operations, and financial condition. **Moreover, we have limited experience in selling the new app- enabled consumer wellness product, and we may be unable to forecast the demand and inventory requirement. This could negatively impact our ability to commercialize our products and have a material adverse effect on our brands, revenues, expenses, results of operations, and financial condition.** Risks Related to Intellectual ~~PropertyOur~~ --- **Property Our** product development initiatives may be delayed or fail to succeed and could also lead to challenging intellectual property rights issues. We may seek to develop new products **, software applications** and technologies, including enhancements of our existing products for nVNS. Developing new products and improving our existing products to meet the needs of current and future patients and consumers require significant investment in research and development. We do not know whether any such product development activities will result in products that meet necessary standards and performance criteria, whether the development will be completed on a timely basis, or, if the development is completed, whether it will lead to market acceptance and commercial success. We will need to carefully manage our introduction of any new products. If potential purchasers of new products believe such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have limited experience in managing product transitions. Even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by changing patient and customer preferences, or the introduction by competitors of products embodying new technologies or features. Delays could occur based on a number of issues, including the need to investigate third party patents and potential infringement matters, which could impair our development and commercialization efforts. ~~41We~~ **43 We** may in the future become involved in lawsuits to protect or enforce our intellectual property, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, thereby hindering our ability to effectively commercialize our existing or future products. If we are unable to obtain, maintain, protect, and enforce our intellectual property, our business will be negatively affected. The markets in which we compete and expect to compete are subject to rapid technological change and frequent litigation regarding patent and other intellectual property rights. It is possible that our patents or licenses may not withstand challenges made by others or protect our rights adequately. Our success depends in large part on our ability to secure effective patent protection for our products and processes in the United States and internationally. We have filed, and intend to continue to file, patent applications for various aspects of our technology and trademark applications to protect our brands and business and copyright applications to protect our software **, digital devices and related software applications, and certain User Manuals, Guides and Instructions for Use for some of our**

commercial products . 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 **, related software applications** and services and make, use, or sell products or offer services that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete. • Patents may not issue from currently pending or future patent applications. • Our already- granted patents and any future patents may not survive legal challenges to their scope, validity, or enforceability, or provide significant protection for us, and they may be challenged in a post grant review or inter partes review proceeding, re- examined or invalidated, and / or may be found to be unenforceable or not cover competing processes, products, or services. • Even if our patents are determined by the U. S. Patent and Trademark Office, or USPTO, foreign patent office, or a court to be valid and enforceable, they may not be drafted or interpreted sufficiently broadly to prevent others from marketing products and services similar to ours or designing around our patents. For example, third parties may be able to develop therapies, or make systems or devices, that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or our contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights from third parties to issued patents or pending patent applications covering such technologies to allow us to commercialize our technology. There may be prior public disclosures of which we are not aware that could invalidate our patents or a portion of the claims of our patents. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable. • Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U. S. Supreme Court and the U. S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications, our ability to obtain patents, or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations. ~~42~~ **44** • 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 **prescription** gammaCore therapy. In addition, we may need to defend our patents from third- party challenges, including interferences, derivation proceedings, re- examination proceedings, post- grant review, inter partes review, third- party submissions, oppositions, nullity actions, or other patent proceedings. We may need to initiate infringement claims or litigation. Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable or may refuse to enjoin the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation could place one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have patent portfolios, including significantly broader patent portfolios, to assert against us, if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation. • We may not be able to accurately estimate or control our future operating expenses in relation to obtaining, enforcing and / or defending intellectual property, which could lead to cash shortfalls. Our operating expenses may fluctuate significantly in the future as a result of the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation. • We may also be forced to enter into cross- license agreements with competitors in order to manufacture, use, sell, offer for sale, import and / or export products or services that are covered by our competitors' intellectual property rights. If we need to use our intellectual property to enter such cross- license agreements, it may compromise the value of our intellectual property due to the fact that our competitors may be able to manufacture, use, sell, offer for sale, import and / or export our patented technology. We rely on **third- party software to develop our products and significant increases in licensing costs or defects in third- party software could harm our business. We rely on software licensed from third parties to develop our products. In addition, we may need to obtain future licenses from third parties**

to use software or other intellectual property associated with our products. There can be no assurance that these licenses will be available to us on acceptable terms, without significant price increases or at all. Any loss of the right to use any such software or other intellectual property required for the development and maintenance of our products could significantly increase our expenses and result in delays in the production of our products until equivalent technology is either developed by us, or, if available from others, is identified, obtained, and integrated, which could harm our business. Any errors or defects in third- party software could result in errors or a failure of our products, which could harm our business. 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 **and related software applications** , 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. **45** 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. **We may introduce products that include related software applications. Software is generally ineligible for patent protection in the United States and other countries. We may not be able to obtain patent claims that adequately cover our software applications. In the event that we do obtain such protection, it may be difficult to enforce any such patents as certain types of software patents are vulnerable to invalidity proceedings in the USPTO and foreign counterparts. Software innovations are often implemented as method patents, which have unique enforcement requirements and restrictions that may make them difficult to enforce against third parties. In addition, it may be difficult to ascertain whether third parties are implementing software that infringes our patents.** ~~43The~~ -- **The** patent positions of pharmaceutical and medical device companies can be highly uncertain and involve complex legal, scientific, and factual questions for which important legal principles remain unresolved. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations, or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Because patent applications in the United States, Europe, and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to conceive or reduce to practice the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or pending patent applications. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability, and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability, and scope of our patents in the United States, Europe, and in other countries cannot be predicted with certainty and, as a result, any patents that we own, or license, may not provide sufficient protection against our competitors. Third parties may challenge any existing patent or future patent we own or license through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with competent jurisdiction may find our patents invalid and / or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services to achieve our business objectives. We may be subject to a third- party pre- issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U. S. patent we own or license. The adoption of the Leahy- Smith America Invents Act, or the Leahy- Smith Act, in September 2011, established additional opportunities for third parties to invalidate U. S. patent claims, including inter partes review and post-grant review proceedings. Outside of the United States, patents we own, or license, may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. In addition, such proceedings are very complex and expensive and may divert our management' s attention from our core business. If any of our patents are challenged, invalidated, circumvented by third parties, or otherwise limited or expire prior to the commercialization of our products, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours, and our business would suffer. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. For example: • others may be able to develop products that are similar to, or better than, ours in a way that is not covered by the claims of our patents; • we might not have been the first to conceive of or reduce to practice the inventions covered by our patents or pending patent applications; • we might not have been the first to file patent applications for our inventions; • any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or • we may not develop additional proprietary technologies that are patentable. ~~44We~~ **46 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. **47** ~~45These~~ -- **These** lawsuits and proceedings, regardless of merit, are time- consuming and expensive to initiate, maintain, defend, or settle, and could divert the time and attention of managerial and technical personnel, which could materially and adversely affect our business. Any such claim could also force use to do one or more of the following: • incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product, service, or technology at issue infringes or violates the third party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third party' s attorneys' fees; • pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non- infringing technology; • stop manufacturing, offering for sale, selling, using, importing, exporting, or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product, service, or technology; • obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all; • redesign our products, services, and technology so they do not infringe or violate the third party' s intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; • enter into cross-licenses with our competitors, which could weaken our overall intellectual property position; • lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others; • find alternative suppliers for non- infringing products and technologies, which could be costly and create significant delay; or • relinquish rights associated with one or more of our patent claims if our claims are held invalid or otherwise unenforceable. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing, or otherwise commercializing our products, services, and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, or financial condition. In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our products. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers, or distributors or may be required to obtain licenses for the products or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services. **48** ~~46Furthermore -~~- **Furthermore** , because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, which could have a material adverse effect on the price of our common stock. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operations, or financial condition. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. In addition to patent, copyright, and trademark protection, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our consultants and vendors, or our former or current employees. We also enter into confidentiality and invention and patent assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to enforce trade secret protection. Further, our competitors may independently develop knowledge, methods, and know- how similar, equivalent, or superior to our proprietary technology. Competitors could purchase our products and attempt to reverse engineer and replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers, or other individuals with access to our proprietary technology and know-how may incorporate that technology and know- how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know- how, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us, and our competitive position could be adversely affected. If our intellectual property is not adequately protected so as to protect our market against competitors' products and processes, our competitive position and business could be adversely affected. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products and processes. As is the case with other pharmaceutical and medical device companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and medical device industries involve both technological and legal complexity and is therefore costly, time- consuming, and inherently uncertain. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and pending patent applications. US Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain other situations. Furthermore, the U. S. Supreme Court and the U. S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. **49**

~~47Obtaining~~ -- **Obtaining** and maintaining patent protection depend on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees, and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business. If our trademarks and trade names are not adequately protected, then, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have used trademarks similar and identical to our trademarks in foreign jurisdictions and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third- party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. If we cannot show access and copying, then, our copyrights may not provide protection for our software and our business may be adversely affected. Copyrights protect works of authorship, such as software, but proving infringement requires a showing of access to the work and copying of the work. Because software is not readily available or accessible, it may be difficult to determine and prove that a third party had access to our software and / or that they copied our software. Because our software may be accessible by obtaining or accessing our product offerings and technology, third parties may be able to download or reproduce our software and reverse engineer our software programs. Software programs can be rewritten in ways that significantly modify it from the original program, which may make it difficult to prove the copying prong of a copyright infringement showing. If we are unable to establish the two prongs of a copyright infringement analysis, then, our copyrights may provide limited or no protection for our software. Copyright infringement suits are expensive, and any damages we seek may be inadequate to compensate us for the costs of litigation and for damage to our business resulting from the copyright infringement. We may not be able to adequately protect our intellectual property rights throughout the world. Filing, prosecuting, and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. We do not have patent rights in certain foreign countries in which a market for our products may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, which could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products and services that are the same as or similar to our products and services, and our competitive position in the international market would be harmed. ~~48We~~ **50 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: ~~49~~ **51** • 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 **; • it is possible that our pending patent applications may not adequately cover our software applications** ; • issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • third parties performing manufacturing or testing for the use of our products or technologies could use the intellectual property of others without obtaining a proper license; • parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property; • we may not develop or in- license additional proprietary technologies that are patentable; • we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business and results of operations. ~~50We~~ **52 We** may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties. We do and may employ individuals who were previously employed at universities or other pharmaceutical or medical device companies, including our licensors, competitors, or potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know- how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs, be a distraction to management and other employees, and could result in customers seeking other sources for the technology, or in ceasing from doing business with us. Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology. Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not be successful in obtaining necessary intellectual property rights to future products through acquisitions and in- licenses. Although we intend to develop products and technology through our own internal research, we may also seek to acquire or in- license technologies to grow our product offerings and technology portfolio. However, we may be unable to acquire or in- license intellectual property rights relating to, or necessary for, any such products or technology from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such products or technology. We may also be unable to identify products or technology that we believe are an appropriate strategic fit for our company and protect intellectual property relating to, or necessary for, such products and technology. The in- licensing and acquisition of third- party intellectual property rights for product candidates are a competitive area, and a number of more established companies are also pursuing strategies to in- license or acquire third- party intellectual property rights for products that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations, and prospects for growth could suffer. In addition, we expect that competition for the in- licensing or acquisition of third- party intellectual property rights for products and technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in- license or acquire the third- party intellectual property rights for products or technology on terms that would allow us to make an appropriate return on our investment. **53** ~~51Our~~ -- **Our** platform utilizes open **-** source software, and any failure to comply with the terms of one or more of these open source licenses could negatively affect our business. Our platform utilizes software governed by open **-** source licenses. The terms of various open **-** source licenses have not been interpreted by United States courts, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market our platform. By the terms of certain open **-** source licenses, if we combine certain proprietary software with open **-** source software in a specified manner, we could be required to release the source code of our proprietary software and make it available under open **-** source licenses. In the event that portions of our platform are determined to be subject to an open **-** source license, we could be required to publicly release the affected portions of our source code, or to re- engineer all or a portion of our technologies, or otherwise be limited in licensing activities, each of which could reduce or eliminate the value of our technologies. In addition to risks related to license requirements, the use of open **-** source software can lead to greater risks than use of third- party commercial software because open **-** source licensors generally do not provide warranties or controls on the origin of the software. Many of the risks associated with the use of open **-** source software cannot be eliminated and could negatively affect our business. ~~Cyber- security~~ **Cybersecurity** 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~~ **cybersecurity** 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, **phishing scams,** 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 **the Company,** our customers and others. Any security breach involving the misappropriation, loss, or other unauthorized disclosure or use of confidential information of our customers or others, whether by us or a third party, could: (i) subject us to civil and criminal penalties; (ii) have a negative impact on our reputation; or (iii) expose us to liability to our customers, third parties, or government authorities. Any of these developments could have a material adverse effect on our business, financial condition, and results of operations. The regulatory environment governing information, cybersecurity, and privacy is increasingly demanding and continues to evolve. ~~The regulatory environment governing information, cybersecurity, and privacy is increasingly demanding and continues to evolve.~~ Personal privacy and data security have become significant issues in the U. S., Europe, and many other jurisdictions where we offer our products. The regulatory framework for privacy and security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. **As a result of a new SEC rule on cybersecurity disclosure, we are required to disclose, pursuant to new Item 1. 05 of SEC Form 8- K, any cybersecurity incident that we determine to be material and describe the material aspects of the nature, scope, and timing of the incident, as well as the material impact or reasonably likely material impact of the incident on us, including our financial condition and results of operations. We will also be required to describe, on a periodic basis, our processes, if any, for the assessment, identification, and management of material risks from cybersecurity threats, and describe whether any risks from cybersecurity threats have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition, our board' s oversight of risks from cybersecurity threats and management' s role in assessing and managing material risks from cybersecurity threats. While any insurance that we may have that covers a specific cybersecurity incident may help to prevent our realizing a significant loss from the incident, it would not protect us from the effects of adverse regulatory actions that may result from the incident or a finding that we had inadequate cybersecurity controls, including the reputational harm that could result from such regulatory actions. Such insurance can be expensive and difficult to procure, and may also be limited and subject to policy terms and significant self- insured retentions. Any such insurance also may be insufficient to cover all losses or all types of claims that may arise. We have incurred significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident and to comply with this new SEC cybersecurity rule. 54** Certain U. S. and foreign laws, such as the federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA), govern the transmission, security, and privacy of individually identifiable information and sensitive health and other personal information that we may obtain or have access to in connection with the operation of our business, including the conduct of clinical research trials or other research studies that may provide us with access to this information. We may be required to make costly system modifications to comply with these data privacy and security requirements. In addition, if we do not properly comply with applicable laws and regulations related to the protection of this information, we could be subject to criminal or civil penalties and sanctions. The California Consumer Privacy Act of 2018 (or CCPA), which became effective on January 1, 2020, requires us to make new disclosures to consumers about our data collection, use, and sharing practices. The CCPA also allows consumers to opt out of certain data sales to third parties, affords new consumer rights, and provides a new cause of action for data breaches with the possibility of significant statutory damage awards as well as injunctive or declaratory relief if there has been unauthorized access, theft, or disclosure of specified personal information due to failure to implement reasonable security procedures. The California Privacy Rights Act (or CPRA), which went into effect on January 1, 2023, with a 12- month look- back period for enforcement purposes, will effectively replace the CCPA. Among other changes, the CPRA expands consumers' rights and has enhanced enforcement mechanisms, such as the creation of a new California privacy agency that will investigate and enforce the CPRA and its promulgating regulations. In addition to the CCPA and the CPRA, all 50 U. S. states have data breach notification laws that, if violated, could result in penalties, fines, and litigation. In addition, many states have implemented or are in the process of implementing related legislation, including state- specific biometric privacy laws that have resulted in class- action lawsuits against businesses. The full impact of these laws on our business is yet to be determined, but it could result in increased operating expenses and additional exposure to the risk of litigation by or on behalf of consumers. Internationally, the General Data Protection Regulation (or GDPR) took effect in May 2018 within the European Economic Area (EEA), and many EEA jurisdictions have also adopted their own data privacy and protection laws in addition to the GDPR. Furthermore, other international jurisdictions, including Singapore, South Korea, China, Brazil, Mexico, and Australia, have also implemented laws relating to data privacy and protection. Although we believe that we are complying with the GDPR and similar laws, these laws are still relatively new. Therefore, as international data privacy and protection laws continue to evolve, and as new regulations, interpretive guidance, and enforcement information become available, we may incur incremental costs to modify our business practices to comply with these requirements. In addition, our internal control policies and procedures may not always protect us from reckless, intentional and / or criminal acts committed by our employees or agents. ~~52~~ **Cybersecurity risks and cyber incidents could result in the compromise of confidential data or critical data systems and give rise to potential harm to customers, remediation and other expenses, expose us to liability under HIPAA, consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business and operations. There are numerous and evolving risks to our cybersecurity and privacy from cyber threat actors. These cyber threat actors, whether internal or external to our company, are becoming more frequent, sophisticated and coordinated in their attempts to access data, including third parties with whom we conduct business through, without limitation, malicious software; data privacy breaches by employees, insiders or others with authorized access; cyber or phishing- attacks; ransomware; attempts to gain unauthorized access to our data and systems; and other electronic security breaches. In the ordinary course of business, we collect and store sensitive information on our network, including intellectual property, proprietary business information and personally identifiable information of individuals, such as our customers and employees. The secure maintenance of this information and technology is critical to our business operations. We are consistently implementing new security measures and technologies to protect the confidentiality, integrity and availability of this data and the systems and devices that store and transmit such data. Although our defenses are monitored and routinely tested internally and by external parties. Threats from malicious persons and groups, new vulnerabilities and advanced new attacks against information systems create enhanced risks of cybersecurity incidents. These incidents can include, but are not limited to, gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may not immediately produce signs of intrusion, we may be unable to anticipate these incidents or techniques, timely discover them, or implement adequate preventative measures. 55 Additionally, in response to the onset of the COVID- 19 pandemic, we modified our business practices to adopt hybrid and remote workplace models for many of our employees. The hybrid and remote workplace models do, however, introduce additional operational risk, including increased cybersecurity risk. These cyber risks include, among other risks, increased phishing, malware, and other cybersecurity attacks, vulnerability to, or disruptions of, our information technology infrastructure and systems to support remote operations, increased risk of unauthorized access, use or dissemination of confidential information, limited ability to restore the systems in the event of a systems failure or interruption, greater risk of a security breach resulting in destruction, alteration or misuse of valuable information, including proprietary business information and personally identifiable information of individuals, all of which could expose us to risks of data or financial loss, litigation and liability. These threats can come from a variety of sources, including criminal hackers, state- sponsored intrusions, industrial espionage and malfeasance by employees, contractors, or other insiders. Cyber threats may be generic, or they may be custom- crafted against our information systems or particular personnel. Over the past several years, cyber attacks have become more prevalent and much harder to detect and defend against. These threat actors may be able to penetrate our security measures, breach our information technology systems, misappropriate or compromise confidential and proprietary information of our company and our customers, cause system disruptions and shutdowns, or introduce ransomware, malware, or vulnerabilities into our products, systems, and networks or those of our** customers and partners. Our network and storage applications, as well as those of our contractors, may be vulnerable to cyber attack, malicious intrusion, malfeasance, loss of data privacy or other significant disruption and may be subject to unauthorized access by hackers, employees, consultants or other service providers. In addition, products, hardware, software or applications we develop, or which we procure from third parties, may contain defects in design or manufacture, security flaws, or other problems that could unexpectedly compromise information security or the operation of our products. Our third- party vendors may experience security incidents of varying severity, including but not limited to increased ransomware attacks, network intrusions, and unauthorized data exfiltration. Targeted cyber-attacks or those that may result from a security incident directed at a third- party vendor could compromise our services and internal systems, resulting in interruptions, delays, or cessation of service that could disrupt business operations for us and our customers. Our proactive measures and remediation efforts may not be successful or timely. Unauthorized parties may also attempt to gain access to our systems or facilities through fraud, trickery or other forms of deceiving our employees, contractors and temporary staff. For example, as disclosed in our Form 10- Q for the quarterly period ended September 30, 2023, it was determined that our internal controls over vendor management, as designed, would not have timely prevented an unauthorized payment based on incorrect vendor information from occurring. As such, we concluded that a material weakness exists in our internal controls over financial reporting. This material weakness did not result in any identified misstatement, and there were no changes to previously reported financial results. Our efforts to remediate this weakness are ongoing, but there can be no assurance that such remediation will succeed nor that our controls will prevent or detect any deceptive practices or the harm stemming there from. We are and may continue to be subject to cybersecurity incidents that bypass our security measures. Such incidents may impact the integrity, availability or privacy of personal health information or other data subject to privacy laws or disrupt our information systems, devices or business, including our ability to deliver products and services to our customers. As a result, cybersecurity, physical security and the continued development and enhancement of our controls, processes and practices designed to protect our enterprise, information systems and data from attack, damage or unauthorized access remain a priority for us but there can be no assurance that our efforts will prevent or mitigate the risks. Moreover, as cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any cybersecurity vulnerabilities. The occurrence of any of these events could result in: • harm to customers and consumers; • business interruptions and delays; • the loss, misappropriation, corruption or unauthorized access of data, confidential information or intellectual property; • litigation, including potential class action litigation, and potential liability under privacy, security and consumer protection laws or other applicable laws; • reputational damage; • significant remediation costs, including liability for stolen customer or employee information, repairing system damage, or providing benefit to affected customers or employees; • increase to insurance premiums; and • foreign, federal and state governmental inquires, violations or sanctions, any of which could have a material, adverse effect on our financial position and results of operations. 56 Any significant interruptions or delays in third- party service and access could result in limited capacity, reduced demand, and loss of customers and adversely affect our business. We rely upon third- parties as service data storage providers, including cloud storage solution providers, for the development, availability or functionality of our medical devices and wellness products, including our next generation Truvaga app- enabled consumer product. Nearly all of our data storage and analytics are conducted on, and the data and content we create associated with sales on our apps and websites are processed through servers hosted by these providers. If our third- party vendors are unable or unwilling to provide the services necessary to support, or if our agreements with such vendors are terminated, our medical devices and wellness products, including the launch and use of our next generation Truvaga app- enabled consumer product, could be significantly affected. Some of our vendor agreements may be unilaterally terminated by the licensor for convenience, and if such agreements are terminated, we may not be able to enter into similar relationships in the future on reasonable terms or at all. Any damage to, or failure of, our systems or the systems of our third- party data centers or our other third- party providers that we may use could result in interruptions to the development, availability or functionality of our medical devices and wellness products, including the launch of our next generation Truvaga app- enabled consumer product. As a result, we could lose consumer data and miss opportunities to acquire and retain consumers, which could potentially result in decreased revenue. If for any reason our arrangements with our data centers or third- party providers are terminated or interrupted, such termination or interruption could adversely affect our business, financial condition, and results of operations. We exercise little control over third- party providers, which increases our vulnerability to problems with the services they provide. We could experience additional expense in arranging for new facilities, technology, services and support. In addition, the failure of third- party data centers or any other third- party providers to meet our requirements could result in interruption in the development, availability or functionality of our medical devices and wellness products, including the launch and use of our next generation Truvaga app- enabled consumer product. The satisfactory performance, reliability, development and availability of our next generation Truvaga app- enabled consumer product is critical to our reputation and our ability to acquire and retain customers, as well as to maintain adequate customer service levels. If the interface of our next generation app is not considered user friendly by our customers or our app does not function correctly, our customers may become frustrated and not order any existing or new wellness products. Our future revenue may depend in part on the number of customers using our app in connection with our next generation consumer product in fulfilling their wellness needs. Unavailability of our app in connection with the use of our next generation consumer product could materially and adversely affect consumer perception of our brand. The occurrence of a natural disaster, power loss, telecommunications failure, data loss, computer virus, an act of terrorism, cyberattack, vandalism or sabotage, act of war or any similar event, or a decision to

close our third- party data centers on which we normally operate or the facilities of any other third- party provider without adequate notice or other unanticipated problems at these facilities could result in lengthy interruptions and affect the launch and use of our next generation Truvaga app- enabled consumer product. Cloud computing, in particular, is dependent upon having access to an internet connection in order to retrieve data. If a natural disaster, blackout or other unforeseen event were to occur that disrupted the ability to obtain an internet connection, we may experience a slowdown or delay in the development, availability or functionality of our medical devices and wellness products, including the launch and use of our next generation Truvaga app- enabled consumer product. While we have disaster recovery arrangements in place, our preparations may not be adequate to account for disasters or similar events that may occur in the future and may not effectively permit consumers to use our medical devices and wellness products, including our next generation Truvaga app- enabled product after launch, in the event of any problems with respect to our systems or those of our third- party data centers or any other third- party facilities. Our disaster recovery and data redundancy plans may be inadequate, and our business interruption insurance may not be sufficient to compensate us for the losses that could occur. If any such event were to occur, our medical devices and wellness products, including the launch and use our next generation Truvaga app- enabled consumer product, could be impaired and our business, financial condition and results of operations may be materially and adversely affected. 57 Failure to protect our information technology infrastructure against cyber attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results. We rely on information technology and telephone networks and systems, including the internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, research and development, product assembly, and distribution. 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. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud- based systems, or failures to adequately scale our data platforms and architectures could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition. Our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, denial- of- service attacks, phishing attacks, ransomware or other malware, attacks by computer hackers (including nation states or state- sponsored organizations), failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors, natural disasters, terrorist attacks, the outbreak of wars or other armed conflicts, or catastrophic events. Although we are developing systems and processes that are designed to protect customer information and prevent data loss and other security breaches, including systems and processes designed to reduce the impact of a security breach at a third- party vendor, such measures cannot provide absolute security. In addition, certain countries have implemented or may implement legislative and technological actions that either do or can effectively regulate access to the internet, including the ability of internet service providers to limit access to specific websites or content. Other countries have attempted or are attempting to change or limit the legal protections available to businesses that depend on the internet for the delivery of their services. If our 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 significantly suffer and we may be subject to litigation, government enforcement actions and other actions for which we could face financial liability and other adverse consequences which may include: • additional government oversight of our operations; • loss of existing customers; • difficulty in attracting new customers; • problems in determining product cost estimates and establishing appropriate pricing; • difficulty in preventing, detecting, and controlling fraud; • disputes with customers, physicians, and other health care professionals; • increases in operating expenses, incurrence of expense, including notification and remediation costs; • regulatory fines or penalties; • individual actions or class actions for damages; • loss of revenues (including through loss of coverage or reimbursement); • product development delays; • disruption of key business operations; and • diversion of attention of management and key information technology resources. 58 Risks Related to Regulation of our ~~Industry~~ **IndustryOur** ~~Our~~ business is subject to extensive governmental regulation that makes it expensive and time consuming for us to bring our **prescription** gammaCore therapy and our general wellness products, Truvaga and TAC- STIM to market in the United States and to expand the use of our **prescription** gammaCore therapy to additional therapeutic indications, and to expand the reach of our **general** wellness initiatives. Our **prescription** gammaCore therapy must comply with regulatory requirements imposed by the FDA in the United States and by similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, extensive agency review processes, and other costly and time- consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. Some of the most important requirements we must comply with include: • the Federal Food, Drug, and Cosmetic Act (FDCA) and the FDA' s implementing regulations (Title 21 CFR); • CE mark requirements of the European Union (or EU) and UKCA mark requirements of the United Kingdom; • Medical Device Quality Management System Requirements (ISO 13485: 2016); • Occupational Safety and Health Administration requirements; • Federal Trade Commission requirements; • health information privacy and security laws, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and comparable state laws; and

• State of New Jersey Department of Health Services legal requirements. Government regulation may impede our ability to conduct clinical trials and manufacture and sell our existing therapy and any future products. Government regulation also could delay our marketing of new products for a considerable period of time and impose costly procedures on our activities. For instance, the FDA and other regulatory agencies may not clear or approve our **prescription** gammaCore therapy in additional therapeutic areas that we may pursue, on a timely basis, if at all. We have recently reduced resources in research and development which may delay our receipt of regulatory approvals for additional indications. Any delay in obtaining, or failure to obtain, such clearances or approvals could negatively impact our marketing of our **prescription** gammaCore therapy and impede our ability to bring future products to market. Moreover, any reclassification, redesignation, or new regulatory treatment of our existing general wellness products in light of applicable law, nonbinding recommendations or other inferences resulting from complex legal analysis and interpretation of the existing regulatory framework governing wellness products and their relational position in the larger FDA scheme of enforcement may negatively impact our marketing and other activities in respect to our **general** wellness and human **brands** ~~performance products~~, Truvaga and TAC- STIM, respectively, and other future marketing and other activities in respect to future **general** wellness business ventures. Even though 510 (k) clearance from the FDA has been received to expand the label for **prescription** gammaCore therapy for several indications, our **prescription** 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 **prescription** gammaCore therapy and on our competitive and financial position. **59** ~~53The~~ -- **The** advertising, marketing, and labeling of medical devices are highly regulated by the FDA and FTC. Our efforts to promote our **prescription** gammaCore therapy, including via direct- to- consumer marketing or social media initiatives, could subject us to additional scrutiny of our communication of risk information, benefits or claims, by the FDA, FTC, or both agencies. Our general wellness product activity is also subject to similar marketing and promotion risk. In 2009, the FTC promulgated nonbinding Guides Concerning the Use of Endorsements and Testimonials in Advertising (or Endorsement Guides), which explained what endorsement practices the FTC views as being unfair or deceptive acts or practices. In 2020, the FTC sought public comments in connection with informal, notice and comment rulemaking on whether the Endorsement Guides should be amended in various ways. The last time the FTC sought similar public comments led to a major revision of the Endorsement Guides. Consequently, the FTC could bring an enforcement action based on practices that are possibly inconsistent with the current Endorsement Guides as the FTC considers any revisions. Under the current Endorsement Guides, advertisements that feature a consumer and convey his or her atypical experience with a product or service are required to clearly disclose the typical results that consumers can generally expect. We cannot be sure that the FTC will not challenge our advertising or other operations in the future, which could have a material adverse impact on our business. Furthermore, as a general matter, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business and prospects for growth. We could also be subject to new international, federal, state, or local regulations that could affect our research and development programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations for an unknown period of time. Compliance obligations under the various domestic and foreign regulations are oftentimes complex and onerous, which contributes to a risk that we could be found to be not compliant with particular requirements. The risk of being found in violation of applicable domestic and foreign regulations, as a consequence of public law- based adjudicatory or other processes (such as administrative law hearings), is further increased by the fact that many of them have not been comprehensively interpreted by regulatory agencies or judicial authorities, particularly with respect to new and emerging technologies, and regulatory provisions are typically open to various interpretations and possible juridical doctrines in certain jurisdictions that imbue greater authority to interpret the law to regulatory authorities under certain conditions or standards. Any significant developments in the FDA or foreign regulatory approval standards and processes, including both legal and policy changes, could also delay, or preclude, the clearance or approval of our products submitted for review. For example, in the United States, as part of the 21st Century Cures Act passed in 2016, Congress enacted several reforms that affect medical device regulation both pre- and post- approval, and FDA implementation and development of guidance in many areas are ongoing. In August 2017, Congress enacted the FDA Reauthorization Act of 2017 (or FDARA), which reauthorized the FDA to collect device user fees, including a new user fee for de novo classification requests, and contained substantive amendments to the device provisions of the FDCA. Among other changes, FDARA mandated that the FDA update and revise its processes for scheduling inspections of device establishments, communicating about those inspections with manufacturers, and providing feedback on the manufacturer' s responses to Form 483s. The statute also mandated that the FDA study the impact of device servicing, including third- party services, and created a new process for device sponsors to request classification of accessory devices as part of the PMA application for the parent device or to request a separate classification of accessory devices. In addition, the FDA is reportedly in the process of reviewing the 510 (k) approval process and criteria and has announced initiatives to improve the current pre- and post- market regulatory processes and requirements associated with infusion pumps and other home- use medical devices, for instance, and, as part of such review efforts, the FDA is evaluating adverse event reporting and recall processes for insulin pumps. Generally, any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market, and distribute existing products. The data contained in our submissions, including data drawn from our clinical trials, may not be sufficient to support clearance or approval of our products or additional or expanded indications. Medical device company stock prices have declined significantly in certain circumstances where companies have failed to meet expectations in regard to the timing of regulatory approval. If the FDA' s response causes product approval delays, or is not favorable for any of our products, our stock price could decline substantially. It is uncertain how potential changes to FDA regulatory approval standards and processes may impact our ability to gain clearance or approval from FDA for our products in the future. ~~54 We depend heavily on revenue from the Department of Defense and the Department of Veterans Affairs for a substantial portion of our business. Changes in the U. S. Government' s priorities, or delays or reductions in spending could have a material adverse effect on our business. Approximately~~ 60 ~~. 8 % of our revenues from operations in fiscal 2022 were from sales directly or indirectly to the programs with the U. S. Department of Defense, primarily the Department of Veterans Affairs, and to a lesser extent the U. S. Air Force. Cost cutting including through consolidation and elimination of duplicative organizations and insurance has become a major initiative for Department of Defense. The funding of our programs may be subject to the overall U. S. government budget and appropriation decisions and processes which are driven by numerous factors, including geo- political events and macroeconomic conditions. Spending levels by government authorities we do business with can be increasingly difficult to predict and are expected to be affected by numerous factors. Such factors include priorities of the Biden administration and the Congress, and the overall health of the U. S. and world economies and the state of governmental finances. We expect that budgetary constraints and concerns related to spending and the national debt will continue to place pressure government spending levels, which could adversely impact funding for purchase of certain of our products, our operations, financial results and growth prospects.~~ Our future success in part depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products or product enhancements that will be accepted by the market in a timely manner. It is important to our business that we build a pipeline of product offerings for treatment of our target indications. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products, or these products may not be accepted by physicians or the payors who financially support many of the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to: • identify and anticipate physician and patient needs properly; • develop and introduce new products or product enhancements in a timely manner; • avoid infringing upon the intellectual property rights of third parties; • demonstrate, if required, the safety and efficacy of new products with data from preclinical and clinical studies; • obtain the necessary regulatory clearances or approvals for new products or product enhancements; • comply fully with FDA and foreign regulations on marketing of new devices or modified products; • provide adequate training to potential users of our products; and • receive adequate coverage and reimbursement for procedures performed with our products. If we do not develop new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, or if our competitors introduce new products with functionalities that are superior to ours, our results of operations will suffer. gammaCore is subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer. The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the European Commission and the EEA member states, competent authorities, and notified bodies. The FDA, FTC, and other U. S., EEA, and foreign governmental agencies and authorities regulate and oversee, among other things, with respect to medical devices: ~~55~~ **61** • design, development, and manufacturing; • testing, labeling, content and language of instructions for use and storage; • clinical trials; • product safety; • risk assessment, and management; • marketing, sales and distribution; • pre- market regulatory clearance and approval; • conformity assessment procedures; • record- keeping procedures; • advertising and promotion; • recalls and other field safety corrective actions, and in the case of the FDA, for example, if the FDA subsequently determines that a report was required for such recall or other field correction action that was not submitted, any subsequent related enforcement actions; • post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; • post- market studies; and • product import and export. The laws and regulations to which we are subject are complex and have tended to become more stringent over time. Legislative or regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs, or lower than anticipated sales. Our failure to comply with U. S. federal and state regulations or EEA or other foreign regulations applicable in the countries where we operate could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures, or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facilities are possible. If any of these risks materialize, our business would be adversely affected. **62** ~~56gammaCore~~ -- **gammaCore** is also subject to extensive governmental regulation in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer. In the EEA, gammaCore must currently comply with the Essential Requirements laid down in (i) Annex I to Directive 93 / 42 / EEC and (ii) EU Medical Device Regulation 2017 / 745, or MDR, on the approximation of the laws of the member states relating to medical devices or the EU Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE mark to gammaCore, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self- assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure that requires the intervention of a notified body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the notified body would audit and examine the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The notified body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device, such as product labeling and instructions for use, are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. gammaCore is a Class IIa medical device in the EU. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent ethics committee. This process can be expensive and time- consuming. Moreover, in May 2017, the EU Medical Devices Regulation 2017 / 745, or MDR was adopted. The MDR repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i. e., without the need for adoption of EEA Member State laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The MDR, among other things, is intended to establish a uniform, transparent, predictable, and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The MDR became applicable on May 26, 2021, with the transition period intended to end on May 26, 2024. While progress has been made on the transition from the MDD to the MDD, a European Commission proposal published on January 6, 2023, stated that the overall number and capacity of conformity assessment (a. k. a., ‘ notified’) bodies remains insufficient to carry out the tasks required of them. In addition, many manufacturers are not sufficiently prepared to meet the strengthened requirements of the MDR by the end of the transition period. This is threatening the availability of medical devices on the EU market. According to an estimation presented by notified bodies to the Medical Device Coordination Group on November 17, 2022, the number of certificates issued by May 2024 may reach around 7, 000 if the current rate of certificate issuance remains the same with no changes to current conditions. Notified bodies estimate that the transition of all Directives’ certificates to MDR certificates could possibly be completed by December 2027. The European Commission’ s “ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017 / 745 and (EU) 2017 / 746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, Brussels, 1. 6. 2023 intends ” to extend the transition period from May 26, 2024 until December 31, 2027 for high- risk Class III and Class IIb implantable devices, and until December 31, 2028 for medium and lower risk Class IIb and Class IIa devices. The gammaCore products (gammaCore Sapphire and gammaCore- S) are EU Class IIa devices. Once applicable, the new regulations will among other things: • strengthen the rules on placing devices on the market and reinforce surveillance once they are available; • establish explicit provisions on manufacturers’ responsibilities for the follow- up of the quality, performance and safety of devices placed on the market; • improve the traceability of medical devices throughout the supply chain to the end- user or patient through a unique identification number; • set up a central database to provide patients, healthcare professionals, and the public with comprehensive information on products available in the EU; and • strengthen rules for the assessment of certain high- risk devices which may have to undergo an additional check by experts before they are placed on the market. **63** ~~57Once~~ -- **Once** applicable, the MDR may impose increased compliance obligations for us to access the EU market. In order to continue to sell gammaCore in Europe, we must maintain our CE Certificate of Conformity for the device and continue to comply with the Medical Devices Directive and with the MDR. The Medical Devices Regulation imposes a number of new requirements on manufacturers of medical devices. This may impact our activities in the EEA and in the United Kingdom, the renewal of our existing CE Certificates of Conformity and conformity assessment related to future bodies. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our notified body (the British Standards Institution), which could impair our ability to market products in the EEA in the future. The United Kingdom’ s withdrawal from the EU (or Brexit) could lead to significant business and legal uncertainty and potentially divergent national laws and regulations in the EU and the United Kingdom. Given the lack of comparable historical precedent, it is unclear what Brexit’ s financial, regulatory, and legal implications would be, and how Brexit would ultimately affect us. However, potentially changing regulatory schemes and tariffs engendered by Brexit may add additional complexity, cost, and delays to the operations of electroCore UK Ltd. and in marketing or selling our products in the United Kingdom. Our revenue and profit, supply, and demand for our products and customer retention and acquisition in both the long term and short term could be adversely affected. Since a significant proportion of the regulatory framework in the United Kingdom was derived from EU directives and regulations, the withdrawal of the United Kingdom from the EU could materially impact the regulatory regime with respect to the CE Certificates of Conformity in the United Kingdom. Importantly, CE Certificates of Conformity issued by a notified body accredited in the EU may no longer be recognized in the United Kingdom. Similarly, notified bodies accredited in the United Kingdom will no longer be able to issue CE Certificates of Conformity. Obtaining new CE Certificates of Conformity or certification for the UK may have a significant impact on our activities. Lastly, Brexit may also disrupt the way that the United Kingdom interprets obligations under CE Certificates of Conformity. If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining FDA clearances, approvals or CE Certificates of Conformity for our future products or product enhancements, our ability to commercially distribute, market, and sell these products could suffer, and, if our general wellness products no longer fall under the scope of applicable FDA guidance, such products may be subject to additional and more comprehensive regulation and / or greater regulatory uncertainty, affecting our ability to commercially distribute, market, and sell such products in the ordinary course of business. Any of our medical device products are subject to rigorous regulation by the FDA, notified bodies, and numerous other federal, state, and foreign governmental authorities. The process of obtaining regulatory clearances, approvals, or CE Certificates of Conformity to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510 (k) of the FDCA, or is the subject of an approved PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510 (k) process if the manufacturer demonstrates that the new product is substantially equivalent to a legally marketed " predicate " device. For novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device, the FDA may determine that the " de novo " process is the appropriate route to market. The " de novo " process is more costly, time consuming, and uncertain than the traditional 510 (k) process. High risk devices deemed to pose the greatest risk, such as life-sustaining, life- supporting, or implantable devices, or devices not deemed substantially equivalent to a legally marketed " predicate " device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510 (k)-clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA' s satisfaction the safety and efficacy of the device for its intended use. Our currently commercialized gammaCore products have been cleared through the 510 (k) process or the " de novo " process. In the future, we may need to submit a PMA or continue to utilize the " de novo " process to expand our labeling claims to include certain indications, which likely will be more costly, time consuming and uncertain than the traditional 510 (k) process. Our general wellness products, Truvaga and TAC- STIM, which in the future may or may not be low risk general wellness products in light of applicability of, and potential, revisions to FDA guidance for such products, and which are not intended for medical use, and which we believe appropriately fall under the scope of current FDA guidance applicable to such products, are not normally subject to the rigorous regulatory processes described in the aforementioned paragraphs. Therefore, some of our products, or product features in certain circumstances, may not be subject to the aforesaid Section 510 (k) process and / or other regulatory requirements in accordance with specific FDA guidance and policies. In addition, some of our products, or product features, may not be subject to statutory device prescription requirements pursuant to various provisions of the FDCA. **64** ~~58Section~~ -- **Section** 3060 (a) of the 21st Century Cures Act amended Section 520 of the FDCA on December 13, 2016, removing certain software functions, including those intended for maintaining or encouraging a healthy lifestyle that are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, from the definition of device in Section 201 (h) of the FDCA. Section 520 (o) (1) (B) of the FDCA states that software that is intended " for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition " is not a device under section 201 (h) of such enactment. In connection with the aforesaid legislative developments, the FDA has issued the aforementioned general wellness guidance in July 2016 and the reissued guidance in 2019, clarifying at each time the FDA' s interpretation of this provision and its application to general wellness products (as defined by the Center for Devices and Radiological Health, which for the purposes of the current guidance mean products that are intended for only general wellness use, as defined in the current general wellness guidance, and that present a low risk to the safety of users and other persons). We recognize that the FDA' s guidance documents, including the current general wellness guidance on low risk, general wellness products, do not create legal obligations. Instead, guidance documents describe the FDA' s contemporary thinking on a topic, which is subject to change, and should be viewed only as legally nonbinding recommendations, unless particular regulatory or statutory requirements are cited to the make the contrary inference. In light of this information, we also recognize that the current guidance does not change or otherwise rescind any legally enforceable requirements of the FDCA or any applicable regulations. Moreover, we acknowledge that the FDA' s general wellness guidance in this respect does not prohibit the FDA from consulting with the Consumer Product Safety Commission (or CPSC) as to whether or not a general wellness product is a consumer product under the CPSC' s authority or a device. The FDA may coordinate with other agencies and authorities, such as the CPSC, in ascertaining appropriate jurisdiction over products. If a product is a device under Section 201 (h) of the FDCA, it is generally excluded from CPSC' s authority over " consumer products " as contemplated under the Consumer Product Safety Act, particularly under Section 2052 (a) (5) (ii) (H). However, CPSC and the FDA may both assert jurisdiction over certain medical devices under other statutory authorities the CPSC is charged with implementing. Subject to continuing analysis and review of considerations included in the FDA, general wellness guidance and any revisions to such guidance and other guidance, we have applied or otherwise made use of the guidance questions in Section 4 of the published FDA low risk, general wellness products guidance document, which assist in determining whether general wellness products are within the scope of such guidance, among other legal review. We acknowledge that such questions should be read in the context of the full written text of the guidance and represent, but do not constitute in and of themselves, the framework described in such guidance. Main considerations, including whether a product has an intended use that relates to maintaining or encouraging a general state of health or healthy activity, whether a product has an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions, whether the product is low risk in that it is not invasive, and not implanted, and does not involve a technology that may pose a risk to the safety or users or other persons if specific regulatory controls are not applied, among other considerations, are particularly relevant to our business involving general wellness products. Descriptions of general wellness products in the aforementioned FDA guidance within Section 3 of the published document are also particularly relevant to our business involving general wellness products. We further acknowledge that the Center for Devices and Radiological Health' s general wellness policy applies only to general wellness products that are deemed to be low risk. In considering whether a product of ours is low risk for purposes of the aforementioned FDA guidance, the FDA recommends the due consideration of whether the Center for Devices and Radiological Health actively regulates products of the same type as the product in question, and this consideration is important to our current and future **general** wellness market engagement. Our business activities involving general wellness products, Truvaga and TAC- STIM may be subject to significant and possibly material and adverse consequences if revisions to FDA guidance or other guidance modify our reasoned beliefs and opinions regarding classification, other legal questions, and compliance with all applicable rules and regulations that apply to our business activities in various ways. Moreover, FDA may disagree with our assessment, potentially subjecting these products to regulation as medical devices. We and our legal advisors strive to regularly keep abreast of all relevant developments in the statutory, administrative, and decisional laws, on federal and, where applicable, state levels, that which influence or inform our general wellness products- related development, marketing, promotion, distribution, and sale, among other activities. In light of the substantial complexity in such laws as well as their potential actual interactive Ness, or perceived overlap or conflict, with the application of the FDA' s existing regulatory approval or clearance processes for medical device products as a result of either official agency changes to applicable **general** wellness guidance, our subsequent legal review of such guidance that differs substantially from earlier legal review of such guidance, or the FDA' s disagreement with our determination regarding the regulatory status of our general wellness products, we may experience adverse and possibly material effects on our ability to commercialize our general wellness products, which could impact our financial condition, operating results, and prospects for growth. Separate and apart from our legal and compliance functions and external advisors, we maintain internal controls and policies and procedures that militate against compliance risk in our **general** wellness line of business and train and educate our sales agents and other personnel on subject matter pertinent to compliance with relevant law in various jurisdictions. **65** ~~59Our~~ -- **Our** failure to comply with U. S. federal, state, and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures, or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible. Foreign governmental authorities and notified bodies that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products internationally, we may be subject to rigorous international regulation in the future. In these circumstances, we would rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries. Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained. Modifications to or expansion of our indications for use of our **prescription** 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~~ **When** we determine that modifications to our products require a new 510 (k) clearance or PMA application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the EU, we must notify our notified body if significant changes are made to the products, or if there are substantial changes to our quality assurance systems affecting those products. Obtaining clearances and approvals can be a time- consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. There is no guarantee that the FDA will grant 510 (k) clearance or PMA approval of our future products, and failure to obtain necessary clearances or approvals for any such future products would adversely affect our overall ability to grow our business. Some of our new products or expanded indications for use will require FDA clearance of a 510 (k) or may require FDA approval of a PMA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510 (k) clearance or PMA of new products, new intended uses, or modifications to existing products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business. **66** ~~60Even~~ -- **Even** if our products are cleared or approved by regulatory authorities, if we or our manufacturers, or suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market. Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review, oversight, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with the FDA' s QSR, and International Standards Organization (or ISO) regulations for the manufacture of our products and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions: • untitled letters, warning letters, fines, injunctions, consent decrees, including FDA orders to repair, replace, or refund the cost of devices, and civil penalties; • unanticipated expenditures to address or defend such actions; • customer notifications for repair, replacement, refunds; • recall, detention or seizure of our products; operating restrictions or partial suspension or total shutdown of production, or interruption of the supply of components from our key component suppliers; • refusing or delaying our requests for 510 (k) clearance or PMA approval of new products or modified products; • operating restrictions; • withdrawing 510 (k) clearances on PMA approvals that have already been granted; • refusal to grant export approval for our products; or • criminal prosecution. If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training, or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other U. S. federal, state, or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. We may also decide to recall a product voluntarily if we find a material deficiency, including unacceptable risks to health, manufacturing defects, design errors, component failures, labeling defects, or other issues. Recalls of our products could divert the attention of our management and have an adverse effect on our reputation, financial condition, and operating results. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements, such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. With regard to QSR administration, the FDA may enforce this regulation through announced (through prior notification) or unannounced inspections that pertain to several facets of our methods and documentation processes of the design, testing, production, control, selection, and oversight of suppliers or contractors; quality assurance; labeling; packaging; storage; complaint handling; shipping; and servicing of our products. **67** ~~61The~~ -- **The** misuse or off- label use of our gammaCore therapy may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in off- label promotion. gammaCore has been CE Marked in the EEA and cleared by the FDA for the acute treatment of eCH in adults, CH prevention, the preventive and acute treatment of migraine headache in the United States in adults and adolescents, and the treatment of Paroxysmal Hemicrania, or HC, in adults. We may only promote or market our gammaCore for its specifically approved or authorized indications as described on the approved or authorized label. We train our marketing and sales force against promoting our products for uses outside of the approved or authorized indications for use, known as " off- label uses. " We cannot, however, prevent a physician from prescribing our product off- label, when in the physician' s independent professional medical judgment, he or she deems appropriate. There may be increased risk of injury to patients if patients attempt to use our product off- label, whether prescribed by physicians or not. Furthermore, the use of our product for indications other than those cleared, approved or authorized by the applicable regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Patients may also misuse our product or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our product is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management' s attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if our products are approved for sale in the United States, and the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or our educational, promotional, and marketing practices in various ways or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and / or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Further, our competitors could bring civil actions under relevant unfair competition and advertising laws should they believe our business activities and product promotional activities are improper. Any of these events could significantly harm our business and results of operations and cause our stock price to decline. While certain U. S. courts have held that truthful, non-misleading, off- label information is protected under the First Amendment under certain circumstances, the FDA continues to take the position that off- label promotion is subject to possible enforcement action. It is also conceivable that other federal, state, or foreign enforcement authorities may take action if they consider our communications, including promotional or training materials, to constitute promotion of an uncleared or unapproved use. If not successfully defended, enforcement actions related to off- label promotion could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In any such event, our reputation could be damaged, adoption of our products could be impaired and we could be subject to extensive fines and penalties. Additionally, we must have adequate substantiation for the claims we make for our products. If any of our claims are determined to be false, misleading or deceptive, our products could be considered misbranded under the FDCA or in violation of the Federal Trade Commission Act. We could also face lawsuits from our competitors under the Lanham Act alleging that our marketing materials are false or misleading. In some instances in our advertising and promotion, we may make claims regarding our products relative to competing products, which may subject us to heightened regulatory scrutiny, enforcement risk, and litigation risks. For instance, the FDA applies an elevated level of review to comparative claims when applying its statutory standards for advertising and promotion, particularly with regard to the requirement that promotional labeling be truthful and not misleading. Differing interpretations as to whether certain communications are consistent with a product' s FDA- required labeling may be more likely in some cases than others, and so, the FDA customarily evaluates communications on a fact- specific basis. ~~62In~~ **68 In** addition, making comparative claims may draw concerns from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor, or that the competitor' s product is inferior, this creates legal risk in that the competitor has possible legal remedies under federal and state false advertising or unfair and deceptive trade practices law (and possibly also state libel law). Such litigation ordinarily implicates relief in equity, such as injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by applicable law. The advertising and promotion of our products is also subject to EEA member states' national laws implementing Directive 93 / 42 / EEC on the approximation of the laws of the member states relating to medical devices, or the Medical Devices Directive and applying the Medical Devices Regulation, Directive 2006 / 114 / EC concerning misleading and comparative advertising, and Directive 2005 / 29 / EC on unfair commercial practices, as well as other EEA member state legislation governing the advertising and promotion of medical devices. EEA member state legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Notwithstanding the risk of legal liability in connection with claims or actions alleging misleading or comparative advertising and promotion, in foreign jurisdictions, we can market a product only if we receive a marketing authorization in the first place and, in some cases, pricing approval, from the appropriate regulatory authorities. The marketing authorization procedures vary among countries and can involve additional testing, and the time required to obtain any required authorization or approval may differ from that required to obtain FDA marketing authorization (s). Foreign regulatory authorization or approval processes may include all of the risks associated with obtaining FDA marketing authorization (s) in addition to other risks. We may not obtain foreign regulatory authorizations or approvals on a timely basis, if at all. Obtaining a marketing authorization from the FDA does not ensure authorization or approval by regulatory authorities in other countries will follow, and authorization or approval by one foreign regulatory authority does not ensure authorization or approval by regulatory authorities in other foreign countries or by the FDA. In addition, in order to obtain the authorization to market our products in certain foreign jurisdictions, we may need to obtain a Certificate to Foreign Government from the FDA. The FDA may refuse to issue a Certificate to Foreign Government in certain instances, including without limitation, during the pendency of any outstanding warning letter. As a result, we may not be able to file for regulatory approvals or marketing authorizations and may not receive necessary approvals or authorizations to commercialize our products in any market outside the United States on a timely basis, or at all. ~~gammaCore~~ **Our products** may in the future be subject to notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results. The FDA, EEA authorities and similar foreign governmental authorities have the authority to request or require the recall of commercialized products in the event of regulatory non- compliance or material deficiencies or defects in design or manufacture that could affect patient safety. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government- mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We must notify the FDA of all device recalls and corrections, and certain classifications of recalls and corrections require more extensive reporting within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls and corrections, even if they are not subject to more extensive reporting requirements. We may initiate voluntary market withdrawals or other market actions involving our gammaCore products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls or corrections when they were conducted. Consumer class action claims and / or product liability claims are a greater risk following a product recall or market withdrawal. ~~63We~~ **69 We** are required to report certain malfunctions, deaths, and serious injuries associated with our products, which can result in voluntary corrective actions or agency enforcement actions. Under the FDA MDR regulations, medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the Directive 93 / 42 / EEC on the approximation of the laws of the member states relating to medical devices or EU Medical Device Directive and the EU Medical Devices Regulation, an incident is defined as any malfunction or deterioration in the characteristics and / or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. Product recalls may materially and adversely affect consumer confidence in our brand and lead to decreased customer demand for our products. Product recalls, withdrawals, or seizures also may lead to increased scrutiny of our operations by federal, state, or international regulatory agencies and increased litigation. Both outcomes could have material adverse effects on our business, results of operations, and financial condition. Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance of our product candidates and to manufacture, market, and distribute our products after clearance is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be. Political change as a result of elections, including presidential and congressional elections, could result in significant legislative and regulatory reforms impacting the FDA' s regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market, and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business. In the EU, on May 25, 2017, the new MDR was adopted, and it entered into application on May 26, 2020. The MDR has introduced substantial changes to the obligations with which medical device manufacturers must comply within the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. ~~64We~~ **70 We** are subject to federal, state, and foreign healthcare laws and regulations, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business. We are subject to healthcare fraud and abuse regulation and enforcement by federal, state, and foreign governments, which could significantly impact our business. In the United States, the laws that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti- Kickback Statute may result in significant civil monetary penalties for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment, and exclusion from participation in government healthcare programs, including Medicare and Medicaid; • the Stark Law, in the event that third- party payors require us to be a durable medical equipment, or DME, supplier or we sell our products directly to providers who are DME suppliers that submit claims to such payors. • The Stark Law prohibits a physician from making a referral for certain designated health services covered by the Medicare program or Medicaid program, including DME, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, and prohibits that entity from billing or presenting a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, significant civil monetary penalties per claim submitted, and exclusion from the federal health care programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA. The statute also provides for significant civil monetary penalties for a circumvention scheme. Various states also have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state; • the federal civil False Claims Act, which prohibits, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The federal civil False Claims Act can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third- party payors. Private individuals can bring False Claims Act " qui tam " actions, on behalf of the government and such individuals, commonly known as " whistleblowers, " may share in amounts paid by the entity to the government in fines or settlement. Penalties for a federal civil False Claims Act violation include three times the actual damages sustained by the government, plus significant mandatory civil penalties for each false claim, and the potential for exclusion from participation in federal healthcare programs. There are also federal criminal false claims and federal civil monetary penalty laws that carry significant monetary and other penalties for submissions of false or fraudulent claims and statements; • HIPAA, as amended, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them; • HIPAA, as amended, and its implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates, relating to the privacy, security and transmission of individually identifiable health information, including mandatory contractual terms as well as privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties, and, in certain circumstances, criminal penalties with fines. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; ~~65~~ **71** • the federal Physician Payments Sunshine Act, implemented as the Open Payments program, which requires certain applicable manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, or CHIP, to report annually to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, and, beginning in 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives; teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. The government may impose significant civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission; and • FCPA and similar worldwide anti- bribery laws in non- U. S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non- U. S. officials for the purpose of obtaining or retaining business; • state and foreign law equivalents of each of the above federal laws, such as state anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require device and drug companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device and drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information, such as the CCPA, many of which differ from each other in significant ways and often are not preempted by HIPAA or other federal privacy and security requirements. These laws and regulations, among other things, constrain our business, marketing, and other promotional activities by limiting the kinds of financial arrangements we may have with physicians or other entities or individuals in a position to purchase, prescribe, or recommend our products. We have entered into consulting agreements and other arrangements with physicians, including some who have ownership interests in us and / or prescribe our products to patients. Compensation under some of these arrangements included the equity interests in our company. We could be adversely affected if regulatory agencies determine our financial relationships with such physicians to be in violation of applicable laws. Due to the breadth of these laws, the narrowness of statutory exceptions, and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. The scope and enforcement of each of these laws are uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Responding to investigations can be time- consuming and costly and can divert management' s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement, for example. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. We have implemented policies and procedures designed to ensure compliance with applicable global laws and regulations, but there can be no assurance that we will be in continuous compliance with all relevant domestic and global regulations, given their multitude, complexity, and changeable nature. If our operations are challenged or found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties; damages; fines; disgorgement; exclusion from governmental health care programs; and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Breakthrough Designation from the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our devices. The FDA' s Breakthrough Devices Program is a voluntary program for certain medical devices and device- led combination products that provide for more effective treatment or diagnosis of life- threatening or irreversibly debilitating diseases or conditions. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510 (k) clearance, and De Novo marketing authorization. The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA' s experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission. While our **prescription** gammaCore nVNS device has received Breakthrough Designation from the FDA for the treatment of posttraumatic stress disorder, or PTSD, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Breakthrough Device designation if it believes that the Designation is no longer supported by data from our clinical development program. **72** ~~66Healthcare~~ -- **Healthcare** legislative reform measures may have a material adverse effect on us. In the United States, there have been, and continue to be, a number of legislative initiatives to contain healthcare costs. In March 2010, the ACA was signed into law, which included, among other things, comparative effectiveness research initiatives and payment system reforms, including shared savings pilots, and other provisions. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal, or replace the ACA will impact the ACA or our business. Any new limitations on, changes to, or uncertainty with respect to the ability of individuals to enroll in governmental reimbursement programs or other third- party payor insurance plans could impact overall demand for our products. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2 % per fiscal year, which went into effect on April 1, 2013 and will remain in effect through ~~2030~~ **2031**, with the exception of a temporary suspension from May 1, 2020 through December 31, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012, was signed into law which, among other things, further reduced Medicare payments to certain providers, including hospitals. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures. ESG matters, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition, and operating results and may damage our reputation. Companies across all industries are facing increasing scrutiny regarding their environmental, social, and governance practices. In particular, we expect many customers will continue to indicate preferences for buying products that are sustainably and responsibly grown and / or made. Changing and unpredictable preferences in this manner may result in increased interest in the sourcing or origin of our components, the recyclability of our products, and the environmental impact of our supply chain, among other areas of interest. Such preferences could require additional transparency, due diligence, and public reporting and could cause us to incur additional costs or to make changes to our business operations. We may also determine that certain changes are required in anticipation of further evolution of consumer preferences and demands. Increased focus on ESG matters may also result in investors reconsidering their investment decisions as a result of their particular assessments of a company' s ESG practices. Moreover, concern over climate change and other environmental sustainability matters has resulted and may in the future result in new or elevated legal and regulatory requirements to reduce or militate against certain impacts to the environment, including greenhouse gas emissions regulations, alternative energy policies, and sustainability initiatives, such as single use plastics. Increased regulatory requirements may be more complex and detailed relative to any sustainability measures we may be currently undertaking or may consider implementing in the future and may cause disruptions in the supply and manufacture of our products or an increase in operating costs. If we fail to achieve any goals, targets, or objectives we may set with respect to ESG matters, if we do not comply with new regulations and laws or meet evolving consumer, investor, industry, or other stakeholder expectations and standards, including those related to potential reporting, or if we are perceived to have not responded appropriately to a growing concern for ESG matters, we may face public or private legal or regulatory actions; the imposition of fines, penalties, or other sanctions; adverse publicity; and decreased total demand from certain customers who may cease buying our products, and the price of our stock could decline. Any of these possible results could adversely and materially harm our reputation or have a materially significant effect on our business, financial condition, or operating results. ~~67~~ **73 Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations which could subject our business to higher tax liability. Our ability to use our net operating losses, or NOLs, to offset future taxable income may be subject to certain limitations which could subject our business to higher tax liability. We may be limited in the portion of NOL carryforwards that we can use in the future to offset taxable income for U. S. federal and state income tax purposes, and federal tax credits to offset federal tax liabilities. Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state law provisions, limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50 % occurs within a three- year period. The statutes limit how much NOLs and tax credits a corporation can use in a tax year after a change in ownership. Avoiding an ownership change is generally beyond our control and even where within our control we may choose to experience an ownership change in connection with a financing or other transaction that might limit our use of NOLs and tax credits in the future. In addition, realization of deferred tax assets, including net operating loss carryforwards, depends upon our future earnings in applicable tax jurisdictions. If we have insufficient future taxable income in the applicable tax jurisdiction for any reason, including any future corporate reorganization or restructuring activities, we may be limited in our ability to utilize some or all of our net operating losses to offset such income and reduce our tax liability in that jurisdiction. See Note 10 " Income Taxes " to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10- K for additional information. There is also a risk that due to regulatory changes or changes to federal or state law, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be**

unavailable either in whole or in part to offset future income tax liabilities. For example, under the Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, which amended certain provisions of the Tax Cuts and Jobs Act of 2017, or TCJA, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. The TCJA, as amended by the CARES Act, also provides that NOLs from tax years that began after December 31, 2017 may offset no more than 80 % of current taxable income annually for taxable years beginning after December 31, 2020. Risks Related to Our Common ~~Stock~~ **StockOur** ~~Our~~ failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock, which could ~~negativelyimpact~~ ------ **negatively impact** the market price and liquidity of our common stock and our ability to access the capital markets ~~. On February 13, 2023, we held a special meeting of stockholders at which the stockholders approved an amendment to the Company' s certificate of incorporation to implement a reverse split of our common stock (the " Reverse Stock Split ") which became effective February 15, 2023. The purpose of the Reverse Stock Split was to seek to increase the price of the common stock and thereby to regain compliance with the minimum closing bid price of $ 1. 00 per share for 10 consecutive trading days as required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5450 (a) (1) (the " Bid Price Rule "). On March 6, 2023, we received a letter from Nasdaq confirming that our common stock had regained compliance with the Bid Price Rule, and as a result, our common stock will continue to be listed on the Nasdaq Capital Market~~ . Any Nasdaq action relating to **failure to comply with Nasdaq' s continued listing requirement including** a **formal** delisting could have a negative effect on the price of our common stock, impair the ability to sell or purchase our common stock when persons wish to do so, and any such delisting action may materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting **or potential delisting** from the Nasdaq Capital Market could also have other negative results, including the potential loss of institutional investor interest and fewer business development opportunities. In the event of any delisting or potential delisting, we may attempt to take actions to restore our compliance with Nasdaq' s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to remain listed or be re- listed, stabilize the market price or improve the liquidity of our common stock, **maintain a minimum closing bid** ~~prevent our common stock from dropping below the Bid Price~~ **price of $ 1. 00 per share as required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing** Rule **5450 (a) (1)** or prevent future non- compliance with Nasdaq' s listing requirements. **If Nasdaq delists our shares of Common Stock from trading on its exchange for failure to meet Nasdaq' s listing standards, we and our stockholders could face significant material adverse consequences including: • a limited availability of market quotations for our securities; • reduced liquidity for our securities; • a determination that our Common Stock is a " penny stock " which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; • a limited amount of news and analyst coverage; and • a decreased ability to issue additional securities or obtain additional financing in the future. In addition, the stock market in general, and the Nasdaq Capital Market, and biopharmaceutical companies in particular, frequently experiences extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of such companies. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and negative impact on the market price of our common stock.** We are currently subject to securities class action lawsuits against us, which could result in adverse outcomes. As described in Item 3. Legal Proceedings, we and certain of our present and past directors and officers have been named in putative securities class action lawsuits alleging violations of the Securities Act of 1933 (" Securities Act ") and the Securities Exchange Act of 1934 (" Exchange Act "). We are generally required to indemnify our current and former directors and officers who are named as defendants in these types of lawsuits. We also have certain contractual indemnification obligations to the underwriters of our initial public offering, or IPO, regarding the securities class action lawsuits. While a certain amount of insurance coverage may be available for **certain** expenses or losses associated with these lawsuits, this coverage **will not cover all such expenses or losses and** may not be sufficient. Although we plan to defend the lawsuits vigorously, there can be no assurances that favorable final outcomes will be obtained. Based on information currently available, we are unable to determine the reasonable probability of loss or a range of potential loss, and accordingly, we have not established an accrual for potential losses, if any, that could result from any unfavorable outcome, and there can be no assurance that these litigation matters, as well as any other lawsuits that might be brought by stockholders, will not result in substantial defense costs and / or judgments or settlements that could have a materially adverse impact on our financial position, results of operations and cash flows. We have broad discretion to determine how to use most of our financial resources and may use them in ways that may not enhance our operating results or the price of our common stock. Our management has broad discretion over the use of most of our financial resources, including proceeds from financings, and we could spend such proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply our financial resources, including the proceeds from such financings and such purchase agreement in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline. An active, liquid and orderly market for our common stock may not continue to be sustained, and our stockholders may not be able to resell their shares at a desired market price and could lose all or part of their investment. Although our common stock is listed on the Nasdaq, we cannot assure you that an active, liquid trading market for our shares will continue to be sustained. A public trading market having the desired characteristics of depth, liquidity, and orderliness depends upon the presence in the marketplace and independent decisions of willing buyers and sellers of our common stock, over which we have no control. The lack of an active market may impair our stockholders' ability to sell their shares at the desired time or at a price that our stockholders consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies or in- license new product candidates using our shares as consideration. We cannot offer any assurance that an active trading market for our common stock will be sustained or how liquid that market may become. As a result, relatively small trades may have a disproportionate impact on the price of our common stock, which may contribute to the price volatility of our common stock and could limit stockholders' ability to sell their shares. In addition, the stock market in general, and the market for smaller biotechnology companies in particular, have experienced extreme price and volume fluctuations that may be unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The above factors could adversely affect the value of our common stock and cause you to lose all or part of your investment. ~~68We are an " emerging growth company, " and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.~~ We ~~are an " emerging growth company, " as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 (" Sarbanes- Oxley Act "), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO (December 31, 2023), (b) in which we~~ have **identified a material weakness in** ~~total annual gross revenue of at least $ 1. 235 billion, or~~ **our** ~~(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 **and determined that our disclosure controls were not effective. If we are unable to remediate this material weakness, or if we experience additional material weaknesses** in the future, **we may not be able to accurately or timely report our financial condition or results of operations and** 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 **maintain effective disclosure controls and procedures and** implement and maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes- Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting. Beginning with our second annual report following our IPO, for our fiscal year ended December 31, 2020, management **has** provided a report on internal control over financial reporting. The Sarbanes- Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we ~~(i) are no longer an " emerging growth company, " as defined by the JOBS Act, and (ii) pursuant to new SEC rules,~~ have annual revenues greater than $ 100 million in the most recent fiscal year for which audited financial statements are available. We do not expect to have our independent registered public accounting firm attest to our management report on internal control over financial reporting for so long as we ~~are an emerging growth company or~~ have annual revenues under $ 100 million. If **and when** we have to design and implement the internal control over financial reporting required to comply with this obligation, such process will be time consuming, costly, and complicated **. In preparation of our condensed consolidated financial statements for our Quarterly Report for the period ended September 30, 2023, we determined that a material weakness in our internal control over financial reporting existed relating to payment security controls and procedures, which weakness did not result in any identified material misstatement, nor any change to previously reported financial results. Management also determined that our disclosure controls were ineffective as of September 30, 2023 due to the existence of this material weakness. In preparing our audited financial statements for the fiscal year ended December 31, 2023, we determined that the material weakness still exists in the Company' s internal controls over financial reporting and our disclosure controls were ineffective. Management is committed to the remediation of the material weakness. Management is actively engaged in the implementation of remediation efforts, as described above, to address the material weakness. To remediate this material weakness, we have undertaken efforts that include but are not limited to, (a) enhancing processes and procedures around payment security, (b) verifying changes to vendor information on a timely basis, and (c) using alternate channels to verify changes to vendor payment information. For more details of the corrective actions, please refer to Item 9A Controls and Procedures. The material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that controls are operating effectively. We can give no assurance that this implementation will remediate this material weakness in our internal control or that material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. If we are unable to remediate this material weakness, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations and 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, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management**

resources to identify, assess and correct any additional material weakness in disclosure or internal control and to otherwise comply with the internal and disclosure controls rules under Section 404 of the Sarbanes- Oxley Act, when applicable . Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management. Our certificate of incorporation and bylaws provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following: • a classified board of directors with three- year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • the required approval of at least ~~662~~ **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; ~~69~~ • the required approval of at least ~~662~~ **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 (or the DGCL). Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years, or, among other exceptions, the board of directors has approved the transaction. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us. Our certificate of incorporation and bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that: • we will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person' s conduct was unlawful; • we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law; • we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification; • we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification; • we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees, and agents. ~~70We~~ **We** do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock. We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or maintain the price at which our holders have purchased it. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware, or Chancery Court, and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: • any derivative action or proceeding brought on our behalf; • any action asserting a breach of fiduciary duty; • any action asserting a claim against us arising under the DGCL, our certificate of incorporation, or our bylaws; and • any action asserting a claim against us that is governed by the internal- affairs doctrine, in each case provided that the Chancery Court has subject matter jurisdiction. If the Chancery Court does not have subject matter jurisdiction, then, such actions may be brought in any state court located in the state of Delaware, or State Courts, or, if and only if the State Courts lack subject matter jurisdiction, in the federal district court for the District of Delaware. This exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by such act or the rules and regulations promulgated thereunder. Our certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, although stockholders cannot waive compliance with the federal securities laws and the rules and regulations adopted thereunder. The enforceability of similar choice of forum provisions in some other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable. The requirements of being a publicly traded company may strain our resources and divert management ~~'~~**’** s attention. As a publicly traded company, we have incurred, and will continue to incur, significant legal, accounting, and other expenses that we did not incur as a private company. In addition, the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 (the ~~"~~**“** Dodd- Frank Act "), as well as rules subsequently implemented by the SEC and Nasdaq, have imposed various requirements on public companies. Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. These rules and regulations may also make it more difficult and more expensive for us to obtain director and officer liability insurance. Failure to comply with these public company requirements could subject us to enforcement actions by the SEC, divert management ~~'~~**’** s attention, damage our reputation, and adversely affect our business, results of operations, or financial condition. In particular, if our independent registered public accounting firm is not able to render the attestation report on our internal control over financial reporting in future annual reports on Form 10- K when required under Section 404 of the Sarbanes- Oxley Act, **or if we are unable to remediate any weakness in our internal control over financial reporting,** it could result in a loss of investor confidence in the accuracy, reliability, and completeness of our financial reports. **The** ~~We expect that the future~~ loss of our " emerging growth company " status and compliance with these additional internal control and auditor attestation requirements will require management to expend additional time while also condensing the time frame available to comply with SEC reporting requirements, which may further increase our legal and financial compliance costs. ~~71Our~~ -- **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 **is** ~~could be~~ highly volatile and could be subject to wide fluctuations in response to various factors, including factors which are beyond our control. These factors include those discussed in the other " Risk Factors " section of this Annual Report and others, such as: • our operating results and financial position; • announcements related to regulatory clearance to market gammaCore for the treatment of various conditions in the United States; • results from, or any delays in, clinical trial programs relating to our product candidates; • announcements **by us or our competitors** of new products ~~by us or our competitors~~ ; • adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain, or sales and marketing activities for our products; • changes or developments in laws or regulations applicable to our products; • any adverse changes in our relationship with any manufacturers or suppliers; • the success of our efforts to acquire or develop additional products; • any intellectual property infringement actions in which we may become involved; • announcements concerning our competitors or the medical device and **general** wellness industries in general; • achievement of expected product sales and profitability; • changes or developments in our commercial strategy and tactics; • manufacture, supply, or distribution shortages; • actual or anticipated fluctuations in our operating results; • FDA or other U. S. or foreign regulatory actions affecting us or our industry, or other healthcare reform measures in the U. S.; • changes in financial estimates or recommendations by securities analysts; • trading volume of our common stock; • sales of our common stock by us, our executive officers, directors, or stockholders; • general economic **, industry, political** and market conditions **including inflation, rising interest rates, new or ongoing health crises and geopolitical events such as the war between Ukraine and Russia, and the war in Israel and the Gaza strip,** and overall fluctuations in the U. S. equity markets; and • the loss of any of our key scientific or management personnel. In addition, the stock markets in general, and the markets for pharmaceutical and medical device stocks in particular, have experienced volatility. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit, and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities. If securities or industry analysts cease publishing regular research or reports about our business or issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts may publish about us or our business. If any of the analysts who cover us were to cease publishing research reports about our business or were to issue an adverse or misleading opinion regarding us, our business model, our intellectual property, or our stock performance, or our stock price, if our operating results fail to meet the expectations of analysts, would likely decline. If one or more of these analysts cease coverage of us or fail to publish research reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. ~~72Sales~~ -- **Sales** of a substantial number of shares of our common stock in the public market could cause our stock price to fall. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Shares that are held by our directors, executive officers, and other affiliates may be subject to restrictions under Rule 144 of the Securities Act, among other restrictions that make such shares not freely tradable in the United States. If these additional shares of common stock are sold pursuant to the applicable exemptions from such restrictions, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. **Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence control over matters subject to stockholder approval. As of December 31, 2023 our executive officers, directors, and holders of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately 24. 4 % of our outstanding common stock. As a result, these stockholders will continue to have a significant influence over all matters requiring stockholder approval. For example, these stockholders may be able to influence 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 you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.** Comprehensive U. S. federal income tax reform could adversely affect us. New legislation or regulation that could affect our tax burden could be enacted by a governmental authority. We cannot predict the timing or extent of such tax- related developments that could have a negative impact on our financial results. U. S. federal legislation affecting the tax laws was enacted in December 2017, in the Tax Cuts and Jobs Act; twice in March 2020, first in the Families First Coronavirus Response Act and again in the CARES Act; in December ~~,~~ 2020 in the Consolidated Appropriates Act, 2021; and in March 2021 in the American Rescue Plan Act of 2021. The Tax Cuts and Jobs Act, among other things, includes changes to U. S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a " worldwide " system of taxation to a modified territorial system. There can be no assurance that the Tax Cuts and Jobs Act will not negatively impact our operating results, financial condition, or our future business operations. This Annual Report does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits, such as carryforwards or tax credits, or a deviation from other tax- related assumptions may cause actual financial results to deviate from previous estimates. Our business and stock price could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities. Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expense and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability, which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. ~~73Item -~~- **Item** ~~IB~~ **1B** . Unresolved Staff CommentsNone **. Item 1C. Cybersecurity Risk management and strategy Managing Material Risks & Integrated Overall Risk Management We are developing processes, including those intended to follow an internal Information Technology (IT) Security Policy, which seek to assess, identify, and manage material risks from cybersecurity threats to the IT systems and information that we create, use, transmit, receive, and maintain. We also seek to integrate these processes and policies into our overall enterprise risk management system and processes. We also maintain an evolving cybersecurity roadmap for our future cybersecurity plans. The processes for assessing, identifying, and managing material risks from cybersecurity threats, including threats associated with our use of third- party service providers, include our efforts to identify the relevant assets that could be affected, determine possible threat sources and threat events, assess threats based on their potential likelihood and impact, and identify controls that are in place or necessary to manage and / or mitigate such risks. In furtherance of our cybersecurity policies and procedures, our IT team has a monthly IT Steering committee meeting, chaired by our Chief Financial Officer (" CFO ") and Chief Strategy Officer, where all new IT projects include a cybersecurity component. Engage Third- parties on Risk Management We engage a range of external experts, including consultants, auditors, and cybersecurity assessors, who assist us in evaluating and testing our cybersecurity systems and processes. These partnerships are intended to give us access to specialized knowledge and insights that can inform our cybersecurity strategies and processes, including as to industry- standard control frameworks and applicable regulations, laws, and standards. Oversee Third- party Risk As part of our evolving cybersecurity roadmap, we plan to implement and conduct security assessments of all third- party service providers before engagement and maintain ongoing monitoring to ensure compliance with relevant cybersecurity standards. Risks from Cybersecurity Threats We have not experienced any material cybersecurity incidents and the expenses we have incurred from any security incidents were immaterial. As a**

result, we do not believe that risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected us, our results of operations and financial condition. However, as discussed under " Risk Factors " in Part I, Item 1A of this Annual Report, cybersecurity threats pose multiple and potentially material risks to us, including potentially to our results of operations and financial condition. See " Risk Factors — 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 strategy and operating results. " As cybersecurity threats become more frequent, sophisticated, and coordinated, it is reasonably likely that we may expend greater resources to continue to modify and enhance protective measures against such security risks. Governance Board of Directors Oversight Our Board of Directors is responsible for exercising oversight of management' s identification and management of, and planning for, risks from cybersecurity threats. While the full Board has overall responsibility for risk oversight, the Board has delegated oversight responsibility related to risks from cybersecurity threats to the Board' s Audit Committee. The Audit Committee discusses with management not less than annually our major financial risk exposures, including those related to data privacy, data security and network security, and management' s program to monitor, assess and control such exposures, including our risk assessment and risk management policies. The Audit Committee reports to the Board as necessary with respect to its activities, including making such reports and recommendations to the Board as it deems necessary and appropriate. Management' s Role Managing Risk The role of the Chief Information Security Officer (CISO) has been assigned to our VP, Information Technology, who has 20 years of IT experience and reports to the CFO. The CISO and the CFO inform the Audit Committee on cybersecurity risks. They provide briefings to the Audit Committee on no less than an annual basis or on an ad hoc basis when needed. These briefings encompass: • Evaluation of existing cybersecurity risks; • Status of ongoing cybersecurity initiatives and strategies from the cybersecurity roadmap; and • Incident reports and learnings from cybersecurity events. Risk Management Personnel Management' s role in assessing, monitoring and managing our material cybersecurity risks is primarily the responsibility of our CISO, reporting to our CFO. Both the CISO and CFO rely on third party experts, including consultants, auditors, and cybersecurity assessors regarding cybersecurity strategies and processes. The CISO manages vendor work related to cybersecurity, and has primary responsibility for the evolving cybersecurity roadmap, remediating known risks, and leading our employee training program, pursuant to which we provide annual privacy and security training for all employees. Our security training incorporates awareness of cyber threats (including but not limited to malware, ransomware and social engineering attacks), password hygiene, incident reporting process, as well as physical security best practices. Our management has also developed security policies and processes which include regular system updates and patches, employee training on cybersecurity and privacy requirements, incident reporting, and the use of encryption to secure sensitive information. In addition, we also regularly perform phishing tests of our employees and update our training plan at least annually. We maintain business continuity and disaster recovery capabilities to mitigate interruptions to critical information systems and / or the loss of data and services from the effects of natural or man- made disasters to our physical operations. Monitor Cybersecurity Incidents The CISO implements and oversees processes for the regular monitoring of our IT systems. This includes the deployment of security measures to identify potential vulnerabilities. In the event of a cybersecurity incident, the CISO runs an incident response plan. This plan includes actions to mitigate the impact and long- term strategies for remediation and prevention of future incidents. Reporting to Board of Directors The CISO regularly informs the CFO of cybersecurity risks and incidents. Furthermore, significant cybersecurity matters, and strategic risk management decisions are escalated to the Board of Directors, which has oversight and may provide guidance on critical cybersecurity issues . Item 2. PropertiesOur principal office is approximately ~~14~~ **22** , ~~000~~ **557** square feet of office, warehouse and assembly space in Rockaway, New Jersey pursuant to a lease that expires in ~~2024~~ **2034** ~~(subject to our right to extend for an additional five years). Our former principal office consisted of approximately 25, 000 square feet of leased office space in Basking Ridge, NJ~~ . Since the spring of 2020, **most** ~~as a result~~ of ~~COVID- 19,~~ our employees ~~previously based in Basking Ridge generally~~ have conducted business remotely ~~. In the fourth quarter of 2020, we formally vacated the Basking Ridge, NJ facility and the lease to this facility was formally terminated in 2021~~ . Management believes our facilities in Rockaway are currently suitable for their intended use. We may in the future add new facilities or expand or relinquish existing facilities as our needs evolve, and we believe that should the need arise, suitable additional or substitute space will be available as needed to accommodate any expansion of our operations. Item 3. Legal ProceedingsOn ~~July 8~~ **September 26** , 2019, and ~~August 1~~ **October 31** , 2019, purported stockholders of ~~our company served putative class action lawsuits in the Superior Court of New Jersey for Somerset County, captioned Paul Kuehl vs. electroCore, Inc., et al., Docket No. SOM- L 000876- 19 and Shirley Stone vs. electroCore, Inc., et al., Docket No. SOM- L 001007- 19, respectively. In addition to our company, the defendants include present and past directors and officers, Evercore Group L. L. C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for our IPO; and two of our stockholders. On August 15, 2019, the Superior Court entered an order consolidating the Kuehl and Stone actions, which proceeded under Docket No. SOM- L 000876- 19. Each plaintiff was appointed a co- lead plaintiff. The plaintiffs filed a consolidated amended complaint, which sought certification of a class of stockholders who purchased our common stock in our IPO or whose purchases are traceable to that offering. The consolidated amended complaint alleged that the defendants violated Sections 11, 12 (a) (2) and 15 of the Securities Act with respect to the registration statement and related prospectus for the IPO. The complaint sought unspecified compensatory damages, interest, costs and attorneys' fees. On October 31, 2019,~~ the Company ~~and the other defendants filed a motion to dismiss the complaint or in the alternative to stay the action in favor of the pending federal action (discussed below). On February 21, 2020, the court granted the defendants' motion to dismiss the consolidated amended complaint with prejudice. On March 2, 2020, the court entered an amended order dismissing the consolidated amended complaint with prejudice. On March 27, 2020, the plaintiffs filed a notice of appeal with~~

~~the N. J. Superior Court- Appellate Division. The appeal was argued on September 27, 2021. On October 8, 2021, the Appellate Division issued an order reversing the decision of the Superior Court. The case has been remanded to the Superior Court for oral argument on the motion to dismiss. On November 11, 2021, the defendants filed a supplemental motion to dismiss based on the forum selection clause in our certificate of incorporation' s. On December 10, 2021, the Superior Court heard argument of the original motion to dismiss and the supplemental motion to dismiss based on the federal forum selection clause. On December 14, 2021, the Superior Court granted the supplemental motion to dismiss based on the federal forum selection clause with prejudice and granted the original motion to dismiss without prejudice. On January 27, 2022, the plaintiffs filed a notice of appeal to the Appellate Division. On April 15, 2022, the plaintiffs filed their appeal brief. The brief of defendant- appellees was filed on May 16, 2022. The appeal is fully briefed. Oral argument is scheduled for April 19, 2023. On September 26, 2019, and October 31, 2019, purported stockholders of our company~~ served putative class action lawsuits in the United States District Court for the District of New Jersey captioned Allyn Turnofsky vs. electroCore, Inc., et al., Case 3: 19- cv- 18400, and Priewe vs. electroCore, Inc., et al., Case 1: 19- cv- 19653, respectively. In addition to ~~our~~ **the** ~~company~~ **Company** , the defendants include present and past directors and officers, and Evercore Group L. L. C., Cantor Fitzgerald & Co., JMP Securities LLC and BTIG, LLC, the underwriters for ~~our~~ **the** IPO. The plaintiffs each seek to represent a class of stockholders who (i) purchased ~~our~~ **the Company' s** common stock in ~~our~~ **the** IPO or whose purchases are traceable to the IPO, or (ii) who purchased common stock between the IPO and September 25, 2019. The complaints each alleged that the defendants violated Sections 11 and 15 of the Securities Act and Sections 10 (b) and 20 (a) of the Exchange Act, with respect to (i) the registration statement and related prospectus for the IPO, and (ii) certain post- IPO disclosures filed with the SEC. The complaints sought unspecified compensatory damages, interest, costs and attorneys' fees. The Priewe case was voluntarily dismissed on February 19, 2020. ~~74In~~ **In** the Turnofsky case, on November 25, 2019, several plaintiffs and their counsel moved to be selected as lead plaintiff and lead plaintiff' s counsel. On April 24, 2020, the Court granted the motion of Carole Tibbs and the firm Bragar, Eagel & Squire, P. C. On July 17, 2020, the plaintiffs filed an amended complaint in Turnofsky. In addition to the prior claims, the amended complaint adds an additional director defendant and two investors as defendants, ~~adds~~ **added** a claim against **us** ~~the Company~~ and the underwriters for violating Section 12 (a) (2) of the Securities Act. On September 15, 2020, **we** ~~the Company~~ and the other defendants filed a motion to dismiss the amended complaint for failure to state a claim. On November 6, 2020, the plaintiffs filed their opposition to the motion to dismiss. The Company and the other defendants filed reply papers in support of the motion on December 7, 2020. Argument of the motion to dismiss occurred on June 18, 2021. On August 13, 2021, the Court dismissed the amended complaint with leave to re- plead. On October 4, 2021, the plaintiffs filed a second amended complaint **in** ~~. On November 17, 2021,~~ the **Turnofsky case. The** defendants moved to dismiss **, and** ~~the new complaint. Briefing~~ **briefing** on the motion was complete on January 7, 2022. On July **13, 2023, the court dismissed the second amended complaint with leave to re- plead. The plaintiffs did not file a third amended complaint. On August 23, 2023, the plaintiffs provided the court with an order of dismissal, and the court entered the order on August 24, 2023. On September 8, 2023, plaintiff Carole Tibbs filed a notice of appeal to the United States Court of Appeals for the Third Circuit. The appeal has been docketed as number 23- 2655. The principal brief of appellant and appendix were filed on January** 5, ~~2022~~ **2024** ~~, the case~~ **. The appellees' brief** was **filed on February 15** ~~reassigned to Judge Zahid N. Quraishi~~ , **2024, and appellant' s reply brief is** ~~who has ordered that he will consider the pending motion to dismiss in~~ due ~~course~~ **on or before March 15, 2024** . Argument of the motion has not yet been scheduled. On March 4, 2021, purported stockholder Richard Maltz brought a purported stockholder derivative action in the United States District Court for the District of New Jersey. The action is captioned Richard Maltz, derivatively on behalf of electroCore, Inc., vs. Francis R. Amato, et al., Case 3: 21- cv- 04135. The defendants include present and past directors and officers of the Company. The plaintiff purports to pursue derivative claims on behalf of the Company in connection with the IPO and actions occurring between the IPO and September 25, 2019. The complaint alleges that demand on the board of directors is excused. The complaint purports to allege claims against the defendants for violating Section 14 (a) of the Exchange Act, breaching fiduciary duties, unjust enrichment and waste of corporate assets. The complaint also purports to allege claims for contribution in connection with the Turnofsky case described above, pursuant to Section 11 (f) of the Securities Act and Sections 10 (b) and 21D of the Exchange Act. The complaint seeks unspecified compensatory damages, interest, costs and attorneys' fees; declaratory relief; and an order requiring changes to corporate governance and internal procedures and a vote on proposed amendments to ~~our~~ **the** ~~bylaws~~ **Bylaws** and ~~certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** . On March 8, 2021, purported stockholder Erin Yuson brought a purported stockholder derivative action in the United States District Court for the District of New Jersey. The action is captioned Erin Yuson, derivatively on behalf of electroCore, Inc., vs. Francis R. Amato, et al., Case 3: 21- cv- 04481. The defendants include present and past directors and officers of the Company. The plaintiff purports to pursue derivative claims on behalf of the Company in connection with a 2019 proxy statement and actions occurring from the IPO through September 25, 2019. The complaint alleges that demand on the board of directors is excused. The complaint purports to allege claims against the defendants for violating Section 14 (a) of the Exchange Act and breaching fiduciary duties. The complaint seeks unspecified compensatory damages, interest, costs and attorneys' fees; declaratory relief; and an order requiring changes to corporate governance and internal procedures and a vote on proposed amendments to ~~our~~ **the** ~~bylaws~~ **Bylaws** and ~~certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** . The plaintiffs in the Maltz and Yuson derivative actions agreed to consolidate and stay those actions. The actions are stayed until and through the resolution of any motion for summary judgment in the Turnofsky federal securities class action. A stipulation to that effect was filed by the plaintiffs on April 14, 2021, and ordered by the court on April 30, 2021. ~~These~~ **On June 9, 2023, the** cases **were administratively dismissed without prejudice** ~~also have been re- assigned to Judge Quraishi~~ . We intend to continue to vigorously defend ~~ourselves~~ **itself** in these matters. However, in light of, among other things, the preliminary stage of these litigation matters, ~~we are~~ **the Company is** unable to determine the reasonable probability of loss or a range of potential loss. Accordingly, ~~we have~~ **the Company has** not established an accrual for potential losses, if any, that could result from any unfavorable outcome, and there can be no assurance that these litigation matters will not result in substantial defense costs and / or judgments or settlements that could adversely affect ~~our~~ **the Company' s** financial condition. We are subject to various claims, complaints ~~,~~ and legal actions in the normal course of business from time to time. ~~We are~~ **The Company is** not aware of any further currently pending litigation for which it believes the outcome could have a material adverse effect on its operations or financial position. ~~We~~ **The Company** expenses associated legal fees including those relating to the stockholder litigation described in ~~Note 13~~ **this Item 3** in the period they are incurred. Item 4. Mine Safety DisclosuresNot applicable.