Risk Factors Comparison 2024-02-23 to 2023-02-21 Form: 10-K

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Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as the other information in this Annual Report, including our financial statements, the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business. Risk Factor Summary Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading " Risk Factors " and should be carefully considered together with other information in this Annual Report on Form 10- K and our other filings with the Securities and Exchange Commission (SEC) before making investment decisions regarding our common stock: • ~~The COVID- 19 pandemic has harmed and continues to affect our business, financial condition, results of operations, and growth. •~~ We are ~~substantially~~ dependent on continued market acceptance in the United States for our 10 kHz Therapy, and the failure of our 10 kHz Therapy to continue to gain market acceptance would negatively impact our business. • Our success depends on our ability to grow the SCS market by generating awareness and demonstrating the benefits of our therapy for treating **pain, including patients suffering from** PDN and NSBP. • We must educate physicians and demonstrate to them the merits of our 10 kHz Therapy compared to those of our competitors. • If our competitors, who are large, well- established companies with substantially greater resources than ours and a long history of competing in the SCS market, are better able to develop and market neuromodulation products (including for new indications, such as PDN) that are safer, more effective, less costly, easier to use or otherwise more attractive than our Senza systems, our business will be adversely impacted. • We have a history of significant losses. If we do not achieve and sustain profitability, our financial condition could suffer. • If third- party payors do not provide adequate coverage and reimbursement for the use of Senza, our revenue will be negatively impacted. • We currently are, and may in the future become, involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products. • If we fail to maintain FDA approval or foreign approval or certification to market and sell Senza, or if such approval or certification is impacted in the future, we will be unable to commercially distribute and market Senza in the United States and abroad. Further, we may not be able to obtain required regulatory approvals or certifications to expand the indications for which we may market and sell Senza. • We are in the process of developing internal manufacturing capabilities for our products, but expect to remain dependent upon third- party manufacturers and suppliers, in some cases sole- or single- source suppliers, making us vulnerable to supply shortages and problems and price fluctuations, which could harm our business. • If we fail to receive access to hospital facilities, our sales may decrease. • If clinical studies for future indications do not produce results necessary to support regulatory clearance, approval or certification in the United States or elsewhere, we will be unable to commercialize our products for these indications. • We are required to maintain high levels of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges. • Senza is subject to extensive governmental regulation, both in the United States and in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer. • We may be 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. • Our stock price has experienced significant volatility and may continue to be volatile. As a result, our stockholders may not be able to resell shares of our common stock at or above the price they paid and such volatility may also adversely impact the value of the 2025 Notes **and Braidwell Warrants** . Risks Related to our Business Our business, financial condition, results of operations and growth have been harmed by the effects of the COVID- 19 pandemic and adverse macroeconomic conditions, both of which continue to affect our business. We are subject to impacts and risks related to public health crises, including epidemics and pandemics such as the COVID- 19 pandemic and its lingering effects, as well as the impacts from adverse macroeconomic conditions. The COVID- 19 outbreak has negatively impacted, and continues to negatively impact, our operations and revenues and overall financial condition as demand for elective procedures remains unpredictable ~~and the number of Senza trials and permanent system implant procedures has not recovered to pre- pandemic levels. The demand for elective procedures has declined due to lowered patient and customer willingness to pursue elective procedures and due to government regulations to focus resources to the COVID- 19 pandemic response rather than elective procedures. Medical procedure rates have similarly been impacted by other effects of the COVID- 19 pandemic, including healthcare system staffing shortages, travel restrictions, quarantine restrictions, global and domestic supply chain disruptions, and new COVID- 19 variants. For example, throughout 2021, the COVID- 19 pandemic negatively impacted the global SCS therapy market, which we estimate decreased by approximately 5 % to 10 %. While restrictions in response to the COVID- 19 pandemic have eased, these challenges may arise again at any time due to the unpredictability of the pandemic, and we continue to experience disruptions to our business as a result of patients and customers continuing to be cautious in restarting elective procedures in light of the continued risk posed by the virus. Additionally, global and domestic supply chains and the timely availability of raw materials and products have been and may continue to be materially disrupted by quarantines, factory slowdowns or shutdowns, border closings and travel restrictions resulting from the COVID- 19 pandemic. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future activities~~ . Our business and

financial performance are significantly impacted by macroeconomic conditions. Global macroeconomic challenges, such as the effects of the ongoing war between Russian and Ukraine, **instability in** the **Middle East** ~~COVID- 19 pandemic~~ , supply chain constraints, market uncertainty, volatility in exchange rates, inflationary trends, lower consumer confidence and evolving dynamics in the global trade environment, have impacted our business and financial performance. Such economic impacts could also impact the decision of patients and customers to seek and undertake elective procedures which would adversely impact our revenue and results of operations. Furthermore, a recession or market correction resulting from ~~the COVID- 19 pandemic or other~~ macroeconomic factors could materially affect our business and the value of our common stock. As a result of the COVID- 19 pandemic, our customers, including hospitals, ASCs and physician offices, ~~have~~ experienced financial hardship and some of them **have not and** may not fully recover. This could lead to some of these customers temporarily or permanently shutting down, filing for bankruptcy or being acquired by larger health systems, leading to reduced procedures and / or additional pricing pressure on our products. The ~~COVID- 19 pandemic has also resulted in a significant increase in unemployment in the United States, Europe and Australia, which may continue even after the pandemic. The~~ occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of Senza systems sold ~~after the pandemic has ended~~ as a result of customer and patient reluctance to seek elective care treatment due to increase patient copays and similar financial considerations, which in turn would materially adversely affect our business, financial condition and results of operations. Adverse macroeconomic conditions and any future impacts from the COVID- 19 pandemic, other pandemics or international tensions, could also result in significant disruption of global economic conditions and consumer trends, as well as a significant disruption in financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity, including our ability to repay our 2. 75 % convertible senior ~~convertible~~ notes due 2025 (the 2025 Notes) **and the Braidwell Term Loans** . Our ability to repay the 2025 Notes **and the Braidwell Term Loans** could also be adversely impacted by higher interest rates which could make it more difficult to access capital on favorable trends, or at all. ~~We are subject to risks related to the global pandemic associated with COVID- 19 and its lingering effects, as well as similar future public health crises. The COVID- 19 outbreak has negatively impacted, and its lingering effects continue to negatively impact our operations and revenues and overall financial condition as demand for elective procedures remains unpredictable and the number of Senza trials and permanent system implant procedures has not recovered to pre- pandemic levels. The magnitude of the risks and uncertainties are unpredictable and could be further aggravated by the spread of new variants of the COVID- 19 virus such as the Delta and Omicron variants, which may be more contagious and / or virulent. During the initial stages of the pandemic, the number of Senza systems procedures performed, similar to other elective surgical procedures, decreased significantly as health care organizations globally prioritized the treatment of patients with COVID- 19. For example, in the United States in the first half of 2020 and more recently in connection with the spread of the Omicron variant, governmental authorities recommended, and in certain cases required, that elective, specialty and other procedures and appointments, be suspended or canceled to avoid non- essential patient exposure to medical environments and potential infection with COVID- 19 and to focus limited resources and personnel capacity toward the treatment of COVID- 19. Additionally, overall patient willingness to pursue elective procedures has decreased due to the pandemic and has not fully recovered. Throughout 2021, the COVID- 19 pandemic negatively impacted the global SCS therapy market, which we estimate decreased by approximately 5 % to 10 %. These challenges may arise again at any time throughout the duration of the pandemic, which is uncertain, and could reduce our revenue while the pandemic continues.~~ Notably, the predictably of trial and permanent implant procedures continues to be challenging to forecast in light of the ~~ongoing~~ **oingering impact of the** pandemic ~~and recent surges in cases caused by the Delta and then Omicron variants~~ . Even if the severity of the pandemic subsides, we ~~are~~ **may be** unable to predict the timing that demand for Senza system procedures may return to ~~historic~~ **historical growth** levels as prospective patients may decide to delay their procedures. As a result of the spread of more contagious and virulent variants, the COVID- 19 pandemic could continue to result in a meaningful delay in patients seeking to have a Senza system trial. ~~Further, we anticipate that the substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers relating to a variety of medical conditions will result in patients seeking to have Senza system trials or implant procedures performed having to navigate limited provider capacity, due to, among other reasons, a growing trend of labor shortages with nurses and other healthcare facility staff.~~ We believe these factors may have an adverse effect on the recovery of the global SCS therapy market and, as a result, the amount of time we predict for our sales to recover following the end of the pandemic. ~~Further, numerous state, local and foreign jurisdictions have imposed, and others in the future may impose, " shelter- in- place " orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID- 19. Multiple times in 2020, the governor of California, where our headquarters are located, issued " shelter- in- place " or " stay at home " orders restricting non- essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders or restrictions resulted in our headquarters closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Other disruptions or potential disruptions include restrictions on our personnel and personnel of partners to travel and access customers for training and case support; delays in approvals or certifications by regulatory authorities and notified bodies; delays in product development efforts; and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our Senza systems. For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the Medical Devices Regulation (EU) No 2017 / 745 (the EU Medical Devices Regulation). In addition, even after the lift of " shelter- in- place " orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID- 19, we continue to experience disruptions to our business as a result of patients and customers continuing to be cautious in restarting elective procedures in light of the continued risk posed by the virus.~~ Global and domestic supply chains and the timely availability of raw materials and products may be materially disrupted by quarantines,

factory slowdowns or shutdowns, border closings and travel restrictions resulting from the COVID- 19 pandemic **or subsequent pandemics** . Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future activities. While the potential economic impact brought by and the duration of COVID- 19 may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity, including our ability to repay our ~~2. 75 % convertible senior convertible notes due 2025 (the~~ 2025 Notes ~~)~~ **and the Braidwell Term Loans** . We expect any ~~further~~ **future** shelter- in- place policies and restrictions on elective surgical procedures worldwide to have a substantial impact on our revenue. ~~In addition, a recession or market correction resulting from the spread of COVID- 19 could materially affect our business and the value of our common stock. During the COVID- 19 pandemic, our customers, including hospitals, ASCs and physician offices, have experienced financial hardship and some of them may not fully recover. This could lead to some of these customers temporarily or permanently shutting down, filing for bankruptcy or being acquired by larger health systems, leading to reduced procedures and / or additional pricing pressure on our products. The COVID- 19 pandemic has also resulted in a significant increase in unemployment in the United States, Europe and Australia, which may continue even after the pandemic. The occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of Senza systems sold after the pandemic has ended.~~ Since our inception, we have devoted substantially all of our efforts to the development and commercialization of Senza and 10 kHz Therapy for the treatment of chronic leg and back pain **. While we have begun to diversify our portfolio of products, such diversification is still early. We therefore remain dependent on the continued market acceptance of our 10 kHz Therapy** . We have expanded our commercial efforts since our initial PMA in May 2015, however, we are still in the early stages of our overall commercialization efforts. For example, in July 2021, we received the first FDA approval for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with painful diabetic neuropathy (PDN) utilizing SCS therapy ~~, and we just recently initiated our commercial rollout~~ . In addition, in January 2022, we received FDA approval of our 10 kHz Therapy for the management of non- surgical back pain (NSBP) (intractable back pain without prior surgery and not a candidate for back surgery). The expansion of our commercial efforts, particularly into the PDN indication, is at **an** ~~a very~~ early stage. While we believe the market for SCS in PDN is substantial, it is **under-** ~~undeveloped~~ -- **developed** and will require substantial marketing and education efforts by our sales force to develop this market, the success of which is very uncertain. We have incurred significant costs, including costs to continue to build our sales force in the United States, and we expect these costs to continue as we ~~initiate~~ **continue** our commercial rollout for the PDN and NSBP markets. If we are unable to achieve significant market acceptance in the United States, our results of operations will be adversely affected as the United States is the principal market for Senza. If we are unsuccessful in our continuing efforts to commercialize our products or are unable to market our products as a result of a quality problem, failure to maintain or obtain additional regulatory approvals or certifications, unexpected or serious complications or other unforeseen negative effects related to our 10 kHz Therapy or the other factors discussed in these risk factors, we would lose our ~~only~~ **primary** source of revenue, and our business will be materially adversely affected. We may be unable to gain broader market acceptance for a number of reasons, including due to the below and as a result of other factors set forth herein: • established competitors with strong relationships with customers, including physicians, hospitals and third- party suppliers; • limitations in our ability to demonstrate differentiation and advantages of our product compared to competing products and the relative safety, efficacy and ease of use of our product; • the limited size of our sales force and the learning curve required to gain experience selling our product; • difficulties and challenges in developing and addressing the PDN and NSBP markets as the first neuromodulation therapy approved for these indications, some of which may be difficult to predict or foresee until later in the commercial rollout; • the inability to obtain sufficient supply of the components for our Senza systems or secure second- source suppliers if our main suppliers are unable to fulfill our orders; • 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. Moreover, physicians and hospitals may not perceive the benefits of our products and may be unwilling to change from the SCS devices they are currently using. Communicating the benefits of Senza and the 10 kHz Therapy to these physicians and hospitals requires a significant commitment by our marketing team and sales organization. Physicians and hospitals may be slow to change their practices because of perceived risks arising from the use of new products. Physicians may not recommend or use Senza until there is more long- term commercial experience to convince them to alter their existing treatment methods, or until they receive additional recommendations from other physicians that our product is effective. We cannot predict when, if ever, physicians and hospitals may adopt use of our product. If we are unable to educate physicians and hospitals about the advantages of our 10 kHz Therapy, do not continue to gain market acceptance of our product, or fail to significantly grow our market share, we will not be able to grow our revenue and our business and financial condition will be adversely affected. Physicians play a significant role in determining the course of a patient' s treatment and the type of product that will be used to treat a patient. An important part of our sales process includes the education of physicians on the safe and effective use of our 10 kHz Therapy and our Senza systems, particularly because Senza and **10 kHz Therapy** ~~high- frequency neuromodulation treatment~~ is relatively new as compared to ~~existing~~ **traditional** low- frequency ~~traditional~~ SCS systems, and is the first non- drug product approved for use in the management of certain types of chronic pain associated with PDN, as well as being the only SCS therapy for the management of NSBP. As a result, our ability to address, develop and grow the markets for our 10 kHz Therapy and, ultimately our success, depends, in large part, on effectively educating physicians about our 10 kHz Therapy, including the results of our pivotal clinical studies. In order for us to sell our products, we must successfully demonstrate to physicians the merits of our 10 kHz Therapy compared to our competitors' products. Acceptance of our 10 kHz Therapy depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost- effectiveness of Senza as compared to our competitors' products, as well as in new indications such as those we have received with respect to PDN and NSBP, and then

communicating to physicians the proper application of our 10 kHz Therapy. Physicians typically need to perform several procedures to become comfortable using 10 kHz Therapy and Senza. If a physician experiences difficulties during an initial procedure or otherwise, that physician may be less likely to continue to use our product or to recommend it to other physicians. As a result, educating physicians on the proper use of Senza is critical to the success of our commercialization efforts. If we are not successful in educating physicians and convincing them of the merits of our 10 kHz Therapy or educating them on the use of Senza, they may not use our Senza systems and we may be unable to increase our sales, sustain our growth or achieve profitability. In addition, we believe receiving support of our products from physicians is essential for market acceptance and adoption. If we do not receive support from physicians or long- term data does not show the benefits of using our 10 kHz Therapy, physicians may not use Senza. In such circumstances, our results of operations would be materially adversely affected. It is also important for our growth that these physicians advocate for the benefits of our products in the broader marketplace. If physicians misuse or ineffectively use our products, it could result in unsatisfactory patient outcomes, patient injuries, negative publicity or lawsuits against us, any of which could have an adverse effect on our business. Our competitors are large, well- established companies with substantially greater resources than we have and have a long history of competing in the SCS market. Our most significant competitors are publicly traded, or are divisions of publicly traded, major medical device companies that have substantially greater financial, technical, sales and marketing resources than we have. The 2022 global market for SCS therapy was estimated to be approximately $ 2. 3 billion, with the United States comprising approximately 80 % of the market at that time. Given the size of the existing and potential market in the United States, we expect that as we work to increase our market position and penetration in the United States our competitors will take aggressive action to protect their current market position. For example, in May 2015, a unit of Boston Scientific, one of our principal competitors, filed with the USPTO two petitions for inter partes review challenging the validity of our U. S. Patent No. 8, 359, 102 (the ‘ 102 patent), which the Patent Trial and Appeals Board (PTAB) at the USPTO denied in November 2015, and, in December 2016 and April 2018, filed lawsuits against us in the U. S. District Court for the District of Delaware alleging that we infringed their patents covering technology related to stimulation leads, batteries and telemetry units, and alleging theft of trade secrets and tortious interference with contract. ~~We~~ **Although those litigations have been resolved substantially in our favor, we expect that we** will **continue to** face significant competition in establishing our market share in the United States **, will continue to face challenges to our intellectual property portfolio,** and may encounter unforeseen obstacles and competitive challenges in the United States. In addition, we face a particular challenge overcoming the long- standing practices by some physicians of using the neuromodulation products of our larger, more established competitors. Physicians who have completed many successful implants using the neuromodulation products made by these competitors 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 revenue growth will slow or decline. Further, a number of our competitors are currently conducting, or we anticipate will be conducting, clinical studies to demonstrate the results of their SCS systems. The results of these studies may be equivalent to, or potentially better than, the results of our pivotal U. S. trial. If our competitors are better able to develop and market neuromodulation products that are safer, more effective, less costly, easier to use or otherwise more attractive than our Senza systems, our business will be adversely impacted. The medical device industry is highly competitive and subject to technological change. Our success depends, in part, upon our ability to establish a competitive position in the neuromodulation market by securing broad market acceptance of our 10 kHz Therapy and our Senza systems for the treatment of approved chronic pain conditions. Any product we develop that achieves regulatory clearance, approval or certification will have to compete for market acceptance and market share. We believe that the primary competitive factors in the neuromodulation market are demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects, pricing and contracting, and salesforce experience and relationships. We face significant competition in the United States and internationally, which we believe will continue to intensify. For example, our major competitors, Medtronic, Boston Scientific and Abbott Laboratories, each has approved neuromodulation systems in at least the United States, Europe, and Australia and have been established for several years. Further, since the launch of our product, these major competitors have all launched new SCS systems: Medtronic launched the Intellis system, Boston Scientific launched the Spectra WaveWriter SCS system, the WaveWriter Alpha SCS system and the Fast- Acting Sub- perception Therapy, and Abbott Laboratories launched the Proclaim system. We believe these competitors will continue to launch new products, waveforms, and datasets to remain competitive. For example, in early 2020 Medtronic announced the acquisition of Stimgenics, a company that has developed a specific waveform (DTM) with a purported mechanism of action, and the results of an RCT which had superior results versus traditional SCS. The DTM waveforms have been launched, and launches such as these could result in a reduction of our differentiation in the marketplace. In addition, in January 2022, Medtronic announced that it had received FDA approval of its Intellis rechargeable neurostimulator and Vanda recharge- free neurostimulator for the treatment of chronic pain associate with diabetic peripheral neuropathy, which will directly compete with Senza in the new PDN market. In addition to these major competitors, we also face competition from companies such as **Curonix (formerly** Stimwave **)** , Saluda, Mainstay Medical and Nalu Medical, and may face competition from Neuspera Medical and Biotronik in the future. These companies are becoming more active in the SCS market. For instance, in the first quarter of 2019, Stimwave received FDA clearance for 10 kHz stimulation, expanding their previous clearance for low frequency therapy; Nalu Medical received FDA clearance in the first quarter of 2019 for their SCS system; and Saluda Medical received FDA clearance of their SCS system in March 2022, received certification in the EU in the third quarter of 2019 for their SCS system and were added to the Prostheses List for the same system in Australia in July of 2020. Furthermore, both Medtronic ~~and~~ **,** Abbott **and Boston Scientific have** received approval to promote their SCS products for the treatment of PDN ~~and~~ , **and Abbot** ~~as~~ **has received approval to promote their SCS products for the treatment of NSBP. As** a result, we are no longer the sole SCS company with ~~this~~ **these** ~~indication~~ **indications** approved. We have also seen increased competition in alternative procedures that attempt to address chronic pain conditions from companies that have not traditionally been our

competitors, including for example minimally invasive surgical procedures and solutions that our physician customers and patients may be more commonly considering ahead of SCS therapy. Additionally, there are other emerging competitors with active neuromodulation system development programs that may emerge in the future. Many of the companies developing or marketing competing products either enjoy or may develop several advantages over us, including: • more experienced sales forces; • greater name recognition; • more established sales and marketing programs and distribution networks; • earlier regulatory approval or certification; • long established relationships with physicians and hospitals; • the ability to offer competitive products at a lower price; • significant patent portfolios, including issued U. S. and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third- party suppliers and distributors; • the ability to acquire and integrate our competitors and / or their technology; • demonstrated ability to develop product enhancements and new product offerings; • established history of product reliability, safety and durability; • the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives; • greater financial and human resources for product development, sales, and marketing; and • greater experience in and resources for conducting R & D, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance, approval or certification for products and marketing approved or certified products. Our competitors may develop and patent processes or products earlier than we do, obtain patents that may apply to us at any time, obtain regulatory clearances, approvals or certifications for competing products more rapidly than we do 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 studies sites and enrolling patients in clinical studies. If our competitors are more successful than we are in these matters, our business may be harmed. We have experienced significant net losses, and have no assurance that we will achieve profitability. We expect to continue to incur losses as we build our U. S. commercial operations and continue to investigate the use of our 10 kHz Therapy to treat other chronic pain conditions. Although we had a net income of $ 3. 0 million for the year ended December 31, 2022, we incurred net losses of $ **92. 2 million and $** 131. 4 ~~million and $ 83. 1~~ million for the years ended December 31, **2023 and** 2021 ~~and 2020~~ , respectively. As of December 31, ~~2022~~ **2023** , our accumulated deficit was $ ~~607~~ **699** . ~~2~~ **4** million. Our prior losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. If our revenue grows more slowly than we anticipate, or if our operating expenses are higher than we expect, we may not be able to achieve profitability and our financial condition could suffer. ~~Our patent infringement lawsuits with Boston Scientific Corporation have caused us to, and may continue to cause us to, incur substantial legal expenses.~~ Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit manufacturing cost of our products. ~~Currently, the~~ **We must obtain and maintain a** gross profit generated from the sale of our ~~Senza systems~~ **products that** is ~~not~~ sufficient to cover our operating expenses. To achieve our operating and strategic goals, we will, among other things, need to reduce the per- unit manufacturing cost of ~~Senza~~ **our products** . This cannot be achieved without increasing the volume of components that we purchase in order to take advantage of volume- based pricing discounts, improving manufacturing efficiency or increasing our volume to leverage manufacturing overhead costs. While we received approval to begin manufacturing our SCS systems in our Costa Rica manufacturing facility in September 2022, which was, at least in part, intended to improve our long- term gross margin, there can be no assurance such actions or efforts to reduce our margins will be successful or not ultimately result in us incurring more costs. If we are unable to improve manufacturing efficiency and reduce manufacturing overhead costs per unit, our ability to achieve profitability will be severely constrained. Any increase in manufacturing volumes is dependent upon a corresponding increase in sales. The occurrence of one or more factors that negatively impact the manufacturing or sales of Senza or reduce our manufacturing efficiency may prevent us from achieving our desired reduction in manufacturing costs, which would negatively affect our operating results and may prevent us from attaining profitability **. If third- party payors do not provide adequate coverage and reimbursement for the use of our products, our revenue will be negatively impacted** . Our success in marketing our products depends and will depend in large part on whether U. S. and international government health administrative authorities, private health insurers and other organizations adequately cover and reimburse customers for the cost of our products. In the United States, we expect to derive nearly all our revenue from sales of our products to hospitals and outpatient medical facilities who typically bill various third- party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare- related organizations, to cover all or a portion of the costs and fees associated with our products and bill patients for any applicable deductibles or co- payments. Access to adequate coverage and reimbursement for ~~SCS~~ procedures using ~~Senza (and~~ our ~~other~~ products ~~in development)~~ by third- party payors is essential to the acceptance of our products by our customers. We believe that SCS procedures using our products are adequately described by existing CPT, HCPCS II and ICD- 10- CM codes for the implantation of spinal cord stimulators and related leads performed in various sites of care, although such codes generally do not specifically describe procedures using either low- frequency or high- frequency stimulation. In the United States, although CMS approved a transitional pass- through payment for High- Frequency Stimulation under the Medicare hospital outpatient prospective payment system effective as of January 1, 2016 through December 31, 2017, our customers currently do not receive separate reimbursement for our products. In addition, effective July 1, 2021, Medicare now requires Prior Authorization for certain hospital outpatient procedures, including SCS procedures. Accordingly, we believe that some of our target customers may be unwilling to adopt Senza over more established or lower- cost therapeutic alternatives already available or that may subsequently become available. Further, any decline in the amount payors are willing to reimburse our customers for SCS procedures using Senza could make it difficult for new customers to adopt Senza and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business. 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 medical device

products and services exists among third- party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. For our traditional chronic back and leg pain market, we believe that favorable coverage and reimbursement of procedures using our products from Medicare and certain commercial payors, such as Aetna, Cigna, Humana, Blue Cross Blue Shield and Kaiser, have contributed to our increase in revenue to date, while we continue to engage in efforts to educate payors on the advantages of 10 kHz Therapy. However, there can be no assurance that all private health insurance plans will cover procedures using ~~the~~ **our** ~~product~~ **products** . ~~We~~ **For example, we** currently have more limited coverage and reimbursement for use of our therapy in PDN and NSBP patients and are working to expand payor coverage to include the use of our 10 kHz Therapy in this patient population. This effort could be costly and could take many years to gain broad acceptance, and there can be no guarantee that it will be successful. For example, effective December 1, 2022, UnitedHealthcare updated its SCS medical coverage policy and added language to indicate SCS devices are not covered for treating chronic intractable back pain without prior spine surgery (NSBP). A significant number of negative coverage and reimbursement decisions by private insurers may impair our ability or delay our ability to grow our revenue. 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 products 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. Further, many international markets have government- managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government- managed systems. If sufficient coverage and reimbursement is not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected. We are currently, and may in the future become, involved in lawsuits to protect or enforce our intellectual property, which are expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, thereby hindering our ability to effectively grow sales of our Senza systems or commercialize future products, if any. If we are unable to obtain, maintain, protect, and enforce our intellectual property, our business will be negatively affected. The market for medical devices is subject to rapid technological change and frequent litigation regarding patent and other intellectual property rights. It is possible that our patents or licenses may not withstand challenges made by others or protect our rights adequately. Our success depends in large part on our ability to secure effective patent protection for our products and processes in the United States and internationally. We have filed and intend to continue to file patent applications for various aspects of our technology and trademark applications to protect our brand and business. 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 / or infringe our intellectual property to compete with our products. We are currently involved in, and in the future may become involved in additional, lawsuits and / or proceedings to protect and enforce our intellectual property rights. These lawsuits and proceedings are expensive and require substantial attention of management. However, we face the risks that: • We may fail to secure necessary patents, potentially permitting competitors to market competing products and make, use or sell products that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete. • Patents may not issue from any of our currently pending or future patent applications. • Our already- granted patents and any future patents may not survive legal challenges ~~, including challenges in the ongoing lawsuit with Boston Scientific,~~ to their scope, validity **, term** or enforceability, or provide significant protection for us, and they may be re- examined or invalidated, and / or may be found to be unenforceable or not cover competing products. • Even if our patents are determined by a court to be valid and enforceable, they may not be drafted or interpreted broadly enough to prevent others from marketing products and services similar to ours. Similarly, others may simply design around our patents. For example, third parties may be able to 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 to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO, to determine priority of invention in the United States. There may be prior public disclosures that could invalidate our inventions or parts of our inventions of which we are not aware. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable. • Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U. S. Supreme Court and the U. S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent

applications, our ability to obtain patents or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations. • Monitoring unauthorized uses of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors' products and services. For example, **in order to enforce certain of our patent rights,** we filed a lawsuit in November 2016 against Boston Scientific Corporation ~~in order to enforce certain of our patents~~ , ~~we filed~~ a lawsuit in February 2019 for patent infringement and false advertisement against Stimwave, ~~we filed~~ a lawsuit in February 2020 for patent infringement against Nalu Medical, and ~~we filed~~ another lawsuit in February 2021 for patent infringement against Boston Scientific. We may in the future seek to enforce our patents or other proprietary rights against other potential infringements. 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 products. 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 also need to initiate infringement claims or litigation. Adverse proceedings such as litigation or challenges to the validity of our patents 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 or other adverse proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop 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 or proceeding could place one or more of our patents at risk of being invalidated, interpreted narrowly or found unenforceable. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have 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, 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, import and / or export our patented technology. For additional information regarding risks related to our intellectual property, see " Risks Related to Intellectual Property. " If we fail to develop and retain an effective direct sales force in the United States, our business could suffer. As we increase our commercial and marketing efforts, we will need to retain, develop and grow the number of direct sales personnel that we employ. We continue to make a significant investment in recruiting and training sales representatives and clinical representatives. There is significant competition for sales personnel experienced in relevant medical device sales. Once hired, the training process is lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products often requires or benefits from direct support from us. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, or if our sales representatives 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. To the extent we hire personnel from our competitors, our new sales representatives will usually be subject to restrictive covenants with their former employers, including non- competition, non- solicitation and / or confidentiality provisions. As a result, 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. We and certain of our new sales representatives have been, ~~continue to be,~~ and may in the future be, subject to allegations that these new hires have violated the non- competition clauses, been improperly solicited or divulged to us proprietary or other confidential information of their former employers. Any of these risks may adversely affect our business **. If we fail to maintain FDA approval or foreign approval or certification to market and sell our products, or if such approval or certification is impacted in the future, we will be unable to commercially distribute and our products in the United States and abroad. Further, we may not be able to obtain required regulatory approvals or certifications to expand the indications for which we may market and sell our products** . We and our products are subject to extensive regulation in the U. S. and elsewhere, including by the FDA and its foreign counterparts. The regulations to which we are subject are complex and have tended to become more stringent over time. 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. The FDA and foreign regulatory authorities enforce these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA or foreign regulatory authorities **'** inspections. For example, while we have received FDA approval of our Senza PMA application, there can be no assurance that approval will be maintained. For example: • we may not be able to maintain to the FDA' s satisfaction that our ~~product~~ **products** ~~is~~ **are** safe and effective for ~~its~~ **their** intended use; • we may fail to comply with the guidelines required by FDA and other agencies to maintain our PMA approval **(s)** ; and • the manufacturing processes and facilities we and

our vendors use may not meet applicable requirements to maintain our PMA approval **(s)** . In addition, we may suffer from product liability or other issues that impact our ability to continue to market **our products** ~~the Senza systems~~ in the United States **or abroad** . Failing to maintain FDA approval or foreign approval or certification could result in unexpected and significant costs for us and consume management' s time and other resources. The FDA or foreign regulatory authorities or notified bodies could ask us to improve or augment manufacturing processes, collect and provide data on the quality or safety of our product or issue us warning letters relating to matters that may result in removal of our product from the market. Additionally, we will be required to obtain FDA approval or notified body certification prior to making any modification to the ~~device~~ **devices** , and the FDA or foreign regulatory authorities may revoke the approval or certification or impose other restrictions if post- market data demonstrates safety issues or lack of effectiveness. If we are unable to obtain and maintain the necessary regulatory approvals or certifications, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited. Further, the failure to obtain approval or certification for new products and new indications ~~, such as painful diabetic neuropathy,~~ on existing products could have an adverse effect on our business, financial condition or results of operations. Modifications to our products may require us to obtain **marketing authorizations** ~~new PMA approvals~~ or ~~approvals of a PMA supplement, or any similar approval or certification~~ **certifications** and if we market modified products without obtaining necessary ~~approvals~~ **marketing authorizations** or certifications, we may be required to cease marketing or recall the modified products until required ~~approvals~~ **marketing authorizations** or certifications are obtained **. In the United States, any modification to a product candidate for which we receive marketing authorization may require us to submit a PMA or PMSA supplement and obtain FDA approval, or to submit a new 510 (k) premarket notification and obtain clearance prior to implementing the change** . Certain modifications to a PMA- approved device may require approval of a new PMA or a PMA supplement, or alternatively a notification or other submission to the FDA. **Similarly, any modification to a 510 (k)- cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, generally requires a new 510 (k) clearance or other marketing authorization. The FDA requires every manufacturer to make such determinations in the first instance, but the FDA may review any manufacturer' s decision.** The FDA may not agree with ~~our~~ **a manufacturer' s** decisions regarding whether ~~a~~ new ~~PMA~~ **clearances** or **approvals are** ~~PMA supplement is~~ necessary. We may make modifications to our approved devices in the future that we believe do not require **prior marketing authorization** ~~approval of a new PMA or PMA supplement~~ . If the FDA disagrees with our determination and requires us to submit a new PMA ~~or ,~~ PMA supplement **or 510 (k) premarket notification** for modifications to our previously approved **or cleared** products, we may be required to cease marketing or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve **or clear** our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. With respect to PMA- approved devices, any changes to the manufacturing processes may require prior approval of a PMA supplement before such changes may be implemented. Any delay or failure in obtaining required approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We obtained EU Medical Devices Regulation certification, effective on January 31, 2023. In the EU, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and the EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. Our growth and success depends on physicians' use of our 10 kHz Therapy to treat chronic back pain, as well as the development and success in the PDN and NSBP markets. ~~Our~~ **Until we are able to fully diversify our product portfolio, our** growth and success ~~is~~ **continue to** ~~dependent~~ **depend** on physicians' acceptance and use of our 10 kHz Therapy to treat chronic back **and leg** pain **,** and our development and success in the markets for our newest indications, PDN and NSBP. We believe a significant limitation of current neuromodulation systems is the limited evidence supporting efficacy of traditional SCS products. Senza utilizes high- frequency stimulation technology capable of delivering waveform of up to 10, 000 Hz **, which** ~~for spinal cord stimulation that~~ has been shown to be effective in the treatment of both leg and back pain and the management of chronic pain associated with PDN and NSBP. However, we may face challenges convincing physicians, many of whom have extensive experience with competitors' SCS products and established relationships with other companies, to appreciate the benefits of the 10 kHz Therapy and, in particular, its ability to treat back pain as well as leg pain, and adopt it for treatment of their patients. If Senza is unable to gain acceptance by physicians for the treatment of **back pain, leg pain,** PDN, NSBP or other pain indications for which its use is approved or certified, our potential to expand the existing neuromodulation market will be significantly limited and our revenue potential will be negatively impacted. Our international operations subject us to certain operating risks, which could adversely impact our results of operations and financial condition. As of December 31, ~~2022~~ **2023** , we sell Senza directly in the Netherlands, Austria, Switzerland, Liechtenstein, United Kingdom, Sweden, Australia, Belgium, Luxembourg, Norway and Germany and through distributors and agents located in Spain, Italy, Slovakia, Turkey and Kuwait. The sale and shipment of Senza across international borders, as well as the purchase of components from international sources, subject us to United States and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non- compliance. Other laws and regulations that can significantly impact us

include various anti- bribery laws, including the U. S. Foreign Corrupt Practices Act, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting. 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; • foreign currency exchange rate fluctuations; • 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 ~~Senza~~ **our products** ; • relative disadvantages compared to competitors with established business and customer relationships; • the imposition of additional U. S. and foreign governmental controls or regulations; • economic instability; • virus epidemics and pandemics such as the COVID- 19 outbreak; • changes in duties and tariffs, license obligations and other non- tariff barriers to international trade, including any retaliatory tariffs or other actions taken by foreign countries in response to the U. S. tariffs imposed and threatened by the United States presidential administration; • the imposition of restrictions on the activities of foreign agents, representatives and distributors; • scrutiny of foreign tax authorities that could result in significant fines, penalties and additional taxes being imposed on us; • laws and business practices favoring local companies; • longer payment cycles; • difficulties in maintaining consistency with our internal guidelines; • difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • the imposition of costly and lengthy new export licensing requirements; • the imposition of U. S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and • the imposition of new trade restrictions. If we experience any of these risks, our sales in non- U. S. jurisdictions may be harmed and our results of operations would suffer. Although we have developed internal manufacturing capabilities for our products, we expect to remain dependent upon third- party manufacturers and suppliers, in some cases sole- or single- source suppliers, making us vulnerable to supply shortages and problems and price fluctuations, which could harm our business. We have recently established internal manufacturing capabilities at our facility in Costa Rica. In connection with our manufacturing operations, we may be forced to devote greater resources and management time than we currently anticipate, particularly in areas relating to operations, quality, regulatory, facilities and information technology. We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing processes. If we experience unanticipated employee shortage or turnover in any of these areas, we may not be able to effectively manage our internal manufacturing operations and we may not achieve the operating efficiencies that we anticipate from developing these capabilities, which may negatively affect our product manufacturing processes or result in difficulties in maintaining compliance with applicable regulatory requirements. In addition, we have limited experience managing manufacturing activities in- house, and as a result, our inexperience could exacerbate the likelihood and / or impact of any of the above factors occurring. Any such problems could seriously harm our business. Even if we are successful in developing our internal manufacturing capabilities, we will continue to rely on a limited number of suppliers who manufacture and assemble certain components of our products. The facilities used by us and third- party manufacturers to manufacture our products must be approved by the FDA and any comparable foreign regulatory authority or **certified by** notified body **for the manufacture of our products** pursuant to inspections or audits that will be conducted after we submit a PMA to the FDA or any comparable filing to a foreign regulatory authority or notified body. We do not control the manufacturing process of, and are completely dependent on, any third- party manufacturers we utilize for compliance with cGMP requirements or similar foreign requirements for manufacture of our products. If we or our third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority or notified body, we or they will not be able to secure and / or maintain regulatory approval or certification for use of these manufacturing facilities. In addition, we have no control over the ability of third- party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority or notified body does not approve or certify these facilities for the manufacture of our products or if it withdraws any such approval or certification in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval or certification for or market our products. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals or certifications, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs and infringement of third- party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our suppliers may also encounter problems sourcing key components due to supply shortages. ~~For example, in 2021, there is a global shortage of microchips.~~ Should this shortage continue **or repeat itself** , our ability to produce and sell goods could be significantly impacted. Our reliance on these third- party suppliers also subjects us to other risks that could harm our business, including: • third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us; • we may not be able to obtain adequate supplies from one or more vendors in a timely manner or on commercially reasonable terms; • we are not a major customer of many of our suppliers, and these suppliers may therefore give

other customers' needs higher priority than ours; • our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of our products, impacting our ability to maintain our ~~PMA~~ **FDA** approval or similar foreign approval or certification, or cause delays in shipment, impacting our ability to meet demand in the United States or international markets; • we may have difficulty locating and qualifying alternative suppliers; • switching components or suppliers may require product redesign and possibly submission to FDA, notified bodies or other foreign regulatory bodies, which could significantly impede or delay our commercial activities; • we may incur additional costs in switching from certain existing suppliers in connection with **the** ~~our planned~~ build- out of our Costa Rica manufacturing facility; • one or more of our sole- or single- source suppliers may be unwilling or unable to supply components of our products, or may supply products that do not meet our product requirements; • other customers may use fair or unfair negotiation tactics and / or pressures to impede our use of the supplier; • the occurrence of epidemic or pandemics ~~, such as the COVID- 19 outbreak~~ , which may cause one or more of our suppliers to close their operations either temporarily or permanently; • the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and • our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements. We may not be able to quickly establish additional or alternative suppliers for commercialization in the United States if necessary, in part because we may need to undertake additional activities to qualify such suppliers as required by the regulatory approval process. Similar risk may exist in foreign jurisdictions. Any interruption or delay in obtaining products from our third- party suppliers, or our inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing products. Given our reliance on certain single- source suppliers, we are especially susceptible to supply shortages because we do not have alternate suppliers currently available. We rely upon third- party, single- source, and in certain cases sole- source, suppliers for many of the components and materials used in our products, and for critical manufacturing and packaging services, and the loss of any of these suppliers could harm our business. A number of the critical components used in our products are supplied to us from single- source, or in certain cases sole- source, suppliers, including **but not limited to:** leads, lead extenders, surgical leads, neurostimulator components and telemetry modules. Our ability to supply our products commercially depends, in part, on our ability to obtain a supply of these components that have been manufactured in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. In some cases, we have not entered into manufacturing, supply or quality agreements with our single- source and sole- source suppliers, some of which supply components critical to our products. We are not certain that our single- source or sole- source suppliers will be able to meet our demand for their products and services, either because of the nature of our agreements with those suppliers, or our limited experience with those suppliers, or due to our relative importance as a customer to those suppliers or otherwise. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to the needs of their other customers. Establishing additional or replacement suppliers for the components or processes used in ~~Senza systems~~ **our products** , if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory authority approval or certification, 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. In addition, from time to time, certain of our suppliers experience interruptions and variances in their manufacturing processes, including suppliers of our leads and batteries. Because we are reliant on these single source suppliers, we are particularly susceptible to supply shortages and, if one of our suppliers were to experience an ongoing or continued manufacturing problem, and, in particular, our leads and battery suppliers, our ability to meet our forecasted commercial demand could be materially and negatively impacted. 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 ~~Senza~~ **our products** would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects. If we fail to properly manage our anticipated growth, our business could suffer. To achieve our revenue goals, we must successfully increase manufacturing output to meet expected customer demand. In the future, we may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate revenue. Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer. **We may not realize the benefits of assets that we have acquired, or will acquire in the future, or other strategic transactions that we have or will consummate. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and out- licensing or in- licensing of intellectual property, products or technologies, similar to our recent acquisition of Vyrsa. The success of our strategic transactions, including the Vyrsa acquisition which recently closed, and any future strategic transactions depends on the risks and uncertainties involved including: • unanticipated liabilities related to acquired companies or joint ventures; • difficulties integrating acquired personnel, technologies, and**

operations into our existing business; • retention of key employees; • diversion of management time and focus from operating our business to the management of acquisition and integration efforts, strategic alliances or joint ventures challenges; • increases in our expenses and reductions in our cash available for operations and other uses; • disruption in our relationships with collaborators or suppliers; and • possible write- offs or impairment charges relating to acquired businesses or joint ventures. If any of these risks or uncertainties occur, including in connection with the recently closed acquisition of Vyrsa, we may not realize the anticipated benefit of such acquisition or strategic transaction. For example, the Vyrsa acquisition is the Company' s first acquisition. For the acquisition to be successful, the Company must effectively integrate the Vyrsa business into the Company, something the Company has never done before. If the Company is not successful in integrating the Vyrsa business, the anticipated benefit may not be achieved. In addition, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses, impairments or write- offs of goodwill or impairments and write-offs of in- process research and development assets, any of which could harm our financial condition. In the United States, in order for physicians to use ~~Senza~~ **our products** , the hospital facilities where these physicians treat patients typically require us to enter into purchasing contracts. The process of securing a satisfactory contract can be lengthy and time- consuming and require extensive negotiations and management time. In the EU, from time to time, certain institutions require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, **have varying demands that we may not be able to meet,** and **thus** we may not be successful in the bidding process. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may stagnate or decrease and our operating results may be harmed. Furthermore, we may expend significant effort in these time- consuming processes and still may not obtain a purchase contract from such hospitals. We rely in part on a small group of third- party distributors to effectively distribute our products in certain **geographies** ~~countries outside the United States~~ . We depend in part on medical device distributors for the marketing and sales of our products in certain **geographies** ~~territories in Europe~~ . We depend on these distributors' efforts to market our products, yet we are unable to control their efforts completely. These distributors typically sell a variety of other, non- competing products that may limit the resources they dedicate to selling ~~Senza~~ **our products** . In addition, we are unable to ensure that our distributors comply with all applicable laws regarding the sale of our products. If our distributors fail to effectively market and sell ~~Senza~~ **our products** 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 offering requires time and resources. To develop and expand our distribution, we must continue to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to maintain positive relationships with our distributors, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize existing distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, our revenue may decrease and our operating results, reputation and business may be harmed. We may face product liability claims that could result in costly litigation and significant liabilities. **Clinical testing,** ~~Manufacturing~~ **manufacturing** and marketing ~~Senza, and clinical testing~~ of our **products** ~~10 kHz Therapy,~~ may expose us to product liability and other tort claims. Although we have, and intend to maintain, liability insurance, the coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. **In** ~~For example, in~~ 2014, the U. S. Supreme Court declined to hear an appeal where the U. S. Court of Appeals for the Ninth Circuit ruled that the Medical Device Amendments of 1976 to the FFDCA did not preempt state laws in a product liability case involving a medical device company. If other courts in the United States adopt similar rulings, we may be subject to increased litigation risk in connection with our products. Product liability claims could negatively affect our reputation, continued product sales, and our ability to obtain and maintain regulatory approval for our products. Clinical studies are necessary to support PMA applications or similar foreign applications or submissions and may be necessary to support PMA supplements or similar foreign applications or submissions for modified versions of our marketed device products. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical study. Adverse outcomes in the post-approval studies could also result in restrictions or withdrawal of approval of the PMA or similar foreign approval or certification. We will likely need to conduct additional clinical studies in the future to support new indications for our products or for approvals, clearances or certifications of new product lines, or for the approval or certification of the use of our products in some foreign countries ~~. For example, we are currently conducting clinical studies for Senza to explore the potential for 10 kHz Therapy to treat certain chronic pain conditions, including chronic upper limb and neck pain and non- surgical refractory back pain. We will likely need to conduct additional clinical studies in the future to support regulatory approval or certification for the use of our products to treat some of these new indications~~ . Clinical testing can take many years, is expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following: • the FDA, Institutional Review Boards (IRBs), ethics committees, competent authorities of the EU member states or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold; • patients do not enroll in, or enroll at a lower rate than we expect, or do not complete a clinical study; • patients or investigators do not comply with study protocols; • the FDA may disagree with our interpretation of the data from our pre- clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre- clinical studies or clinical trials, which could further delay the clearance or approval of our products and similar risk exists in foreign jurisdictions; • patients do not return for post- treatment follow- up at the expected rate; • patients experience serious or unexpected adverse

side effects for a variety of reasons that may or may not be related to our products such as the advanced stage of co- morbidities that may exist at the time of treatment, causing a clinical study to be put on hold; • sites participating in an ongoing clinical study withdraw, requiring us to engage new sites; • difficulties or delays associated with establishing additional clinical sites; • third- party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or perform in a manner inconsistent with the investigator agreement, clinical study protocol, good clinical practices, other FDA, IRB or ethics committee requirements, and other foreign regulations governing clinical studies; • third-party organizations do not perform data collection and analysis in a timely or accurate manner; • regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies; • changes in federal, state, or foreign governmental statutes, regulations or policies; • interim or final results are inconclusive or unfavorable as to immediate and long- term safety or efficacy; • the study design is inadequate to demonstrate safety and efficacy; or • the statistical endpoints are not met. In addition, disruptions caused by ~~the COVID- 19 pandemic~~ **macroeconomic factors, or global or local disruptions,** may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting **,** or completing our planned and ongoing clinical studies. Clinical failure can occur at any stage of the testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or non- clinical studies in addition to those we have planned. Our failure to adequately demonstrate the safety and effectiveness of any of our devices would prevent receipt of regulatory clearance, approval or certification and, ultimately, the commercialization of that device or indication for use. We could also encounter delays if the FDA or foreign regulatory authorities concludes that our financial relationships with investigators results in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical study site or the utility of the clinical study itself. Principal investigators for our clinical studies may serve as scientific advisors or consultants to us from time to time and receive cash compensation and / or equity- based awards 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 foreign regulatory authorities concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical study site may be questioned and the utility of the clinical study itself may be jeopardized, which could result in the FDA or foreign regulatory authorities or notified bodies refusing to accept the data as support for our future applications. Any such delay or rejection could prevent us from commercializing any of our products currently in development. Even if our products are approved in the United States, Australia and certified in the EU, comparable regulatory authorities of additional foreign countries and / or notified bodies must also approve the manufacturing and marketing of our products in those countries. Approval or certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, Australia or the EU, including additional preclinical studies or clinical studies. Any of these occurrences may harm our business, financial condition and prospects significantly. Even though we may generate positive data to support the use of our therapy and products for market expansion opportunities, and receive approval or certification to expand our indications for use to include additional indications, internal and external factors may make it more difficult for these additional indications and market expansion opportunities, or any other indications or other market expansion opportunities we may pursue in the future, to be commercially successful. Even if we get approval or certification to expand our indications for use or generate positive data to support the use of our therapy and products for other market expansion opportunities, internal and external factors may make it more difficult for such expanded indications or uses to be commercially successful. These factors include, among others, the following: • the perceived efficacy and safety of our therapy and products for such additional indications or uses by healthcare professionals; • the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team, for such new additional indications or uses; • our ability to offer our therapy and products for such additional indications or uses for sale at competitive prices; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • education and awareness of patients, treating physicians and referring physicians concerning the use of our therapy and products for such additional indications or uses; • sufficient third- party coverage or reimbursement for such additional indications or uses; • natural disasters, ~~including~~ pandemics ~~such as the COVID- 19 pandemic,~~ and political unrest that could inhibit our ability to promote such new indications or uses and can negatively affect product demand by creating obstacles for patients to seek treatment and undergo elective procedures; and • the ability of our competitors to obtain similar approvals ~~, such as Medtronic' s recent PDN approval,~~ and to more successfully commercialize on such market expansion opportunities. For example, even though we have received approval for 10 kHz Therapy for the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with PDN and the management of NSBP (intractable back pain without prior surgery and not a candidate for back surgery), we will still be required to educate patients and healthcare professionals of the benefits of our therapy and products for the treatment of PDN and NSBP. If we are unable to successfully educate patients and healthcare professionals, including referring physicians, we will not be able to establish our 10 kHz Therapy as a viable treatment option for eligible PDN and NSBP patients. ~~Further, we will also be required to either engage and build, or to otherwise contract, a salesforce network to market 10 kHz Therapy for the treatment of PDN. Any such effort could be costly and time- consuming, and there can be no guarantee that it will be successful.~~ In addition, we will ~~also~~ need **to continue** to establish payor acceptance of 10 kHz Therapy as a treatment option within the PDN and NSBP patient communities, a process that may not be successful and could take many years to gain broad acceptance. In addition to the foregoing factors, for our therapy for patients with NSBP to be commercially successful **may** ~~it will~~ require physicians who treat chronic back pain patients with back surgery to refer those patients to other physicians to perform an SCS procedure. As a result of the above factors, any future indications or uses of our therapy and products we may pursue may not be successfully commercialized and as a result, our business and operating results may be harmed. 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 **most of our** other employees are at- will employees, and therefore may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel likely would involve significant time and costs, may significantly delay or prevent the achievement of our business objectives and may harm our business. In addition, many of our employees have become, or will soon become, vested in a substantial amount of our stock or be able to exercise a substantial number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Further, our employees' ability to exercise those options and sell their stock in a public market may result in a higher than normal turnover rate. Our future success also depends on our ability to retain executive officers and other key employees and attract new key employees. Many executive officers and other employees in the neuromodulation and medical device industry are subject to strict non- competition, non- solicitation and / or confidentiality agreements with their employers, including our main competitors Medtronic ~~plc~~, Boston Scientific and Abbott Laboratories. Our competitors may allege breaches of, and seek to enforce, such non- competition, non- solicitation and / or confidentiality agreements or initiate litigation based on such agreements ~~, particularly now that we have entered the U. S. market~~. Such litigation, whether or not meritorious, may impede our ability to attract, hire or utilize executive officers and other key employees who have been or are currently employed by our competitors. Our success depends in part on not infringing the patents or violating the other proprietary rights of others. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. Significant litigation regarding patent rights occurs in the medical industry. Whether merited or not, it is possible that U. S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. For example, on December 9, 2016, Boston Scientific filed a patent infringement lawsuit alleging our manufacture, use and sale of the Senza system infringes certain of Boston Scientific' s patents covering technology related to stimulation leads, batteries and telemetry units. On April 27, 2018, Boston Scientific filed a second lawsuit alleging patent infringement, theft of trade secrets, and tortious interference with contract. **Although those lawsuits have been resolved, we may face other similar lawsuits in the future.** 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 and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, sell, and / or export our products. For example, our major competitors, Medtronic, Boston Scientific and Abbott Laboratories, each have significant patent portfolios covering systems, sub- systems, methods, and manufacturing processes. These competitors may have one or more patents for which they can threaten and / or initiate patent infringement actions against us and / or any of our third- party suppliers. Our ability to defend ourselves and / or our third- party suppliers may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or juries. Further, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages and / or attorneys' fees. From time to time and in the ordinary course of business, we may develop non- infringement and / or invalidity positions with respect to third- party patents, which may or not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us. We may receive in the future, particularly as a public company, communications from patent holders, including non- practicing entities, alleging infringement of patents or other intellectual property rights or misappropriation of trade secrets, or offering licenses to such intellectual property. ~~Any~~ **Similarly, any** claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following: • stop selling, making, using, or exporting products that use the disputed intellectual property; • obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all; • incur significant legal expenses; • pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful; • if a license is available from a third- party, we may have to pay substantial royalties, upfront fees or grant cross- licenses to intellectual property rights for our products and services; • pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; • find non- infringing substitute products, which could be costly and create significant delay due to the need for prior FDA authorization; • find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; and / or • redesign those products or processes that infringe any third- party intellectual property, which could be costly, disruptive, and / or infeasible. From time to time, we may be subject to legal proceedings and claims with respect to intellectual property. For more information regarding ~~our~~ **any** ongoing litigation ~~with Boston Scientific~~ **(s)**, see the section titled " Legal Proceedings " included under Part I, Item 3 of this Annual Report. Even if resolved in our favor, litigation or other legal proceedings relating to

intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, that we do not control. 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 and the value of the 2025 Notes **and / or the Braidwell Warrants** . Additionally, because we often do not control the timing of the public announcements, there is the potential for these announcements to be made during market hours, necessitating a halt in the trading of our common stock for periods of time. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. If any of the foregoing occurs, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the neuromodulation industry grows, the possibility of intellectual property infringement claims against us increases. In addition, we may indemnify our customers, suppliers and international distributors against claims relating to the infringement of the intellectual property rights of third parties relating to our products, methods, and / or manufacturing processes. Third parties may assert infringement claims against our customers, suppliers, or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, suppliers 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 they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, or our suppliers may be forced to stop providing us with products. Similarly, interference or derivation proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. An unfavorable outcome in these or any other such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. We may also become involved in other proceedings, such as re- examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. For example, two of our competitors, Boston Scientific and Medtronic, ~~have~~ filed oppositions in the EU with respect to certain of our patents. Boston Scientific ~~has~~ filed an entitlement action against us in the German courts **(which has seen been reslved in our favor)** . In addition, an anonymous petitioner ~~has~~ filed an opposition before the China National Intellectual Property Administration against one of our patents in China (which was dismissed, but for which the anonymous petitioner has filed an appeal). Defending our position in proceedings such as these will require management' s time and attention, as well as financial costs. Given the competitive environment in which we operate, we expect additional challenges to our intellectual property portfolio as we continue commercialization of ~~Senza~~ **our products** in the United States and abroad. An unfavorable outcome in these or any other such proceedings could cause us to lose valuable intellectual property rights and / or be unable to enforce our intellectual property rights, which could invite increased competition thereby materially harming our business. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act (the Leahy- Smith Act) was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and may affect patent litigation. The changes also switched the United States patent system from a " first- to- invent " system to a " first- to- file " system. Under a " first- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, in particular, the first- to- file provisions, only became effective on March 16, 2013 ~~. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business~~ . The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. 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 **the value, validity, enforceability, and patent terms of** our patents or patent applications **,** and our ability to obtain additional patent protection in the future. We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. In addition, many of our executive officers and key employees have worked for our major competitors (or companies acquired by these competitors), which include Boston Scientific, Medtronic and Abbott Laboratories. Although we have procedures in place that seek to prevent our employees and consultants from using

the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may in the future be subject to ~~claims~~ **allegations** that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. For example, in April 2018, Boston Scientific filed such suit against us, claiming trade secret misappropriation. While we ~~believe~~ **believed** the Boston Scientific claim ~~lacks~~ **lacked** merit **and ultimately prevailed** ~~, even if we are successful in defending against the Boston Scientific claim or any other such claims~~ , litigation necessarily results in substantial costs and ~~could be~~ a distraction to management. **We may be subject to similar lawsuits in the future.** If our ~~defense~~ **defenses** to litigation ~~claims~~ - **claim (s)** ~~fails~~ - **fail** , in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products would have a material adverse effect on our business, and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and 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 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 or 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 **ultimately** 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 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 methods, our competitive position could be adversely affected, as could our business. Risks Related to our Financial and Operating Results Our operating results may vary significantly from quarter to quarter, which may negatively impact our stock price in the future. Our quarterly revenue and results of operations may fluctuate from quarter to quarter due to, among others, the following reasons: • the impact of ~~the COVID- 19 pandemic and~~ adverse macroeconomic **and geopolitical** conditions, such as interest rate increases, inflationary pressures, recession fears and lower consumer confidence, on reduced demand for elective procedures and healthcare provider staffing shortages; • physician and payor acceptance of our products ~~and 10 kHz Therapy~~ ; • our success in initiating patient trials for the 10 kHz Therapy and converting those trials into permanent implants; • our ability to develop and grow the SCS market by convincing physicians and patients to use our therapy to treat PDN and NSBP, and convincing payors to cover such procedures; • the effectiveness of the development of new markets for SCS, including PDN and NSBP; • fluctuations in our expenses associated with inventory buildup or write- downs from analyzing our inventory for obsolescence or conformity with our product requirements; • fluctuations in the average sales prices of our products, in particular due to pricing pressure from competitors; • fluctuations in the expenses related to initiating, pursuing and defending lawsuits; • buying patterns of our customers; • the timing, expense and results of our commercialization efforts in the United States and elsewhere, R & D activities, clinical studies and regulatory approvals or certifications; • the introduction of new products and technologies by our competitors; • the productivity of our sales representatives; • difficulties in collecting receivables related to our sales ~~in the United States~~ ; • fluctuations in expenses as a result of expanding our commercial operations and operating as a public company; • supplier, manufacturing or quality problems with our products; • changes in our pricing policies or strategies or in the pricing policies or strategies of our competitors; • adverse macroeconomic conditions, such as increased interest rates or recession fears, resulting in capital market disruptions or volatility making it difficult for us to access such markets; • changes in coverage amounts or government and third- party payors' reimbursement policies; and • **other** market volatility and other macroeconomic factors ~~, including those resulting from the COVID- 19 pandemic~~ Because of these and other factors, it is likely that in some future period our operating results will not meet investor expectations or those of public market analysts. Any unanticipated change in revenues or operating results is likely to cause our stock price to fluctuate. New information may cause investors and analysts to revalue our business, which could cause a decline in our stock price. We may choose, or need, 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 our expenses will increase as we continue to build a commercial sales force in the United States, including for our ~~recently~~ approved indications ~~of~~ **in** PDN and NSBP, investigate the use of our 10 kHz Therapy for the treatment of other chronic pain conditions, continue to otherwise grow our business, including potentially acquiring other businesses or technologies, manage the maturity of the 2025 Notes **and the Braidwell Term Loans** , and continue to operate as a public company. In particular, we believe that we will continue to expend substantial resources for the foreseeable future on the commercialization of ~~Senza~~ **our products** in the United States, as well as the growth of our sales and marketing efforts and sales representative training, seeking additional foreign regulatory approvals or certifications, the preparation and submission of regulatory filings and the clinical development of any other product candidates or indications we may choose to pursue. These expenditures will also include costs associated with manufacturing and supply as well as marketing and selling ~~Senza~~ **our products** in the United States and elsewhere, and any other future products approved for sale, R & D, conducting preclinical studies and clinical studies and obtaining regulatory approvals or certifications. We believe that our growth will depend, in part, on our ability to fund our commercialization efforts, particularly in the United States, and our efforts to develop our **products** ~~Senza systems and 10 kHz Therapy~~ for the treatment of additional chronic pain indications and develop technology complementary to our current product. In order to further enhance our R & D efforts, pursue product expansion opportunities or acquire a new business or products that are complementary to our business, we may choose to seek additional funds. If we are unable to raise funds on favorable terms, or at all, the long- term growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including: • the costs of commercializing our products in the United States and elsewhere, including costs associated with product sales, marketing, manufacturing and distribution; • our ability to maintain the average sales price of our products, in particular if we face pricing pressure from competitors' products; • the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights ~~, including, in particular, the costs of enforcing our patent rights in the action we filed against Boston Scientific and in defending against Boston Scientific' s action against us~~ ; • the R & D activities we intend to undertake in order to expand the chronic pain indications and product enhancements that we intend to pursue; • whether or not we pursue acquisitions or investments in businesses, products or technologies that are complementary to our current business; • the degree and rate of market acceptance of our products in the United States and elsewhere; • changes or fluctuations in our inventory supply needs and forecasts of our supply needs; • our need to implement additional infrastructure and internal systems; • our ability to hire additional personnel to support our operations as a public company; and • the emergence of competing technologies or other adverse market developments. To finance these activities, we may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. We may be unable to raise funds on favorable terms, or at all. 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, these securities could have rights superior to holders of our common stock ~~and~~ **,** the 2025 Notes **, the Braidwell Term Loans and the Braidwell Warrants** , and 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, product candidates, or products that we otherwise would not relinquish. If we do not obtain additional resources, our ability to capitalize on business opportunities will be limited, we may be unable to compete effectively and the growth of our business will be harmed. **Covenants in our loan documents may restrict our business and operations and if we do not effectively manage our covenants, our financial condition and results of operations could be adversely affected.. The Braidwell Credit Agreement, as well as the indenture governing our 2025 Notes, contain certain affirmative, operating and financial covenants. These covenants could adversely affect our ability to operate our business, our liquidity or our results of operations, and our inability to comply with any of these covenants could result in a default under the Braidwell Credit Agreement or indenture governing our 2025 Notes, which could result in an increase the applicable interest rate or all amounts borrowed under the applicable debt instrument, together with accrued interest and other fees, to become due and payable. If our indebtedness under the Braidwell Term Loans or the 2025 Notes were to be accelerated, we may not have sufficient cash available to repay the amounts due, and we may be forced to seek an amendment to the applicable loan or note terms or obtain alternative financing, which may not be available to us on acceptable terms, if at all. In addition, if we are unable to repay outstanding borrowings when due or upon an event of default, in the case of the Braidwell Term Loans, the lender would also have the right to proceed against the collateral, including substantially all of our assets, granted to secure the indebtedness under the debt obligation. If the applicable lender proceeds against the collateral, such assets would no longer be available for use in our business, which would have a significant adverse effect our business, financial condition and results of operations** As a result of the need to maintain substantial levels of inventory, we are subject to the risk of inventory obsolescence and expiration, which may lead to inventory impairment charges. Our products consist of a substantial number of individual components. In order to market and sell ~~Senza~~ **our products** effectively, we often must maintain high levels of inventory. In particular, as we continue to market and sell ~~Senza~~ **our products** in the United States, we intend to maintain our high levels of inventory in order to meet our estimated demand and, as a result, incur significant expenditures associated with such levels of inventory. The manufacturing process requires lengthy lead times, during which components of our products may become obsolete, and we may over- or underestimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third-party manufacturers exposes us to greater lead times increasing our risk of inventory obsolescence comparatively, and we would be required to record an impairment charge, as we did in 2020, 2021 and 2022. Furthermore, our products have a limited shelf life due to sterilization requirements, and part or all of a given product or component may expire and its value would become

impaired. We have also experienced inventory write- downs as a result of inventory that did not meet our product requirements. In addition, as we release later generations of products that contain advancements or additional features, the earlier generations may become obsolete. If our estimates of required inventory are too high, we may be exposed to further inventory obsolescence risk. In the event that a substantial portion of our inventory becomes obsolete or expires, or in the event we experience a supply chain imbalance as described above, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. The seasonality of our business creates variance in our quarterly revenue, which makes it difficult to compare or forecast our financial results. Our revenue fluctuates on a seasonal basis, which affects the comparability of our results between periods. For example, due to the seasonality of buying patterns and implant volumes of distributors, hospitals and clinics, the industry generally experiences lower revenues in the first and third quarters of the year and higher revenues in the fourth quarter. We have experienced these industry trends to a greater degree than in our initial U. S. commercial launch phase, although normal purchasing patterns have been disrupted since the COVID- 19 pandemic. These seasonal variations are difficult to predict accurately, may vary amongst different markets, and at times may be entirely unpredictable, which introduce additional risk into our business as we rely upon forecasts of customer demand to build inventory in advance of anticipated sales. We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations. A portion of our business is located outside the United States and, as a result, we generate revenue and incur expenses denominated in currencies other than the U. S. dollar, a majority of which is denominated in Euros, British Pounds and Australian Dollars. As a result, changes in the exchange rates between such foreign currencies and the U. S. dollar could materially impact our reported results of operations and distort period to period comparisons. Fluctuations in foreign currency exchange rates also impact the reporting of our receivables and payables in non- U. S. currencies. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations. In addition, to the extent that fluctuations in currency exchange rates cause our results of operations to differ from our expectations or the expectations of our investors, the trading price of our common stock and the value of the 2025 Notes could be adversely affected. In the future, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on our results of operations. Our ability to use our net operating losses and tax credits to offset future taxable income and taxes may be subject to certain limitations. In general, under Section 382 of the U. S. Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change net operating loss (NOL) carryforwards and other tax attributes, such as research and development tax credits, to offset post- change taxable income and taxes. As a result of our June 2015 underwritten public offering, we have experienced a Section 382 " ownership change. " We currently believe that this " ownership change " will not inhibit our ability to utilize our NOLs prior to expiration. However, we may experience additional ownership changes as a result of subsequent changes in our stock ownership, some of which changes may be outside our control. As a result, we may not be able to utilize a material portion of our NOLs and tax credits, even if we achieve profitability and generate sufficient taxable income in the future. If we are limited in our ability to use our NOLs and tax credits in future years as a result of ownership changes, we will pay more taxes than if we were able to fully utilize our NOLs and tax credits. This could materially and adversely affect our results of operations. As of December 31, ~~2022~~ **2023**, we had federal NOLs of $ ~~538~~ **543**. ~~3~~ **2** million, of which $ ~~330~~ **344**. ~~8~~ **1** million was generated in fiscal year 2018 and thereafter, which can be carried forward indefinitely under the Tax Cuts and Jobs Act (the 2017 Tax Act), as well as state NOLs of $ ~~300~~ **337**. ~~0~~ **1** million, of which $ ~~28~~ **82**. 2 million may be carried forward indefinitely. If not utilized, the remaining federal NOLs will begin to expire in 2032 and the state NOLs will begin to expire in ~~2023~~ **2024**. Risks Related to Regulation of our Industry ~~Senza is~~ **Our products are** 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 competent authorities of the EU member states. The FDA and other U. S. and foreign governmental agencies and authorities and notified bodies regulate and oversee, among other things, with respect to medical devices: • design, development and manufacturing; • testing, labeling, content and language of instructions for use and storage; • clinical studies; • product safety; • marketing, sales and distribution; • pre- market regulatory clearance, approval and certification; • conformity assessment procedures; • record- keeping procedures; • advertising and promotion; • recalls and other field safety corrective actions; • post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; • post- market studies; and • product import and export. The laws and regulations to which we are subject are complex and have tended to become more stringent over time. Legislative or regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. Our failure to comply with U. S. federal and state regulations or 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, approvals or certifications, 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. Our business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to expand the potential indications for which ~~Senza is~~ **our products are** approved or certified or introduce new or improved products. Our products must comply with regulatory requirements imposed by the FDA in the United States and similar agencies or bodies in foreign jurisdictions. These requirements **may** involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, extensive agency review processes or notified bodies 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: • FFDCA and the FDA' s implementing regulations (Title 21 CFR); • EU legislation on medical devices; • Medical Device Quality Management System Requirements (ISO 13485: 2016); • Occupational Safety and Health Administration requirements; and • California Department of Health Services requirements. Government regulation may impede our ability to conduct clinical studies and to manufacture and sell our existing and 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. Foreign regulatory agencies or notified bodies may not approve or certify **our current** ~~Senza and any of our~~ **or** future products on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals or certifications could negatively impact our marketing of any future products and reduce our product revenues. Our products 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 products and on our business and financial position. Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our R & D programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, ~~on~~ **in** February ~~23, 2022~~ **2024**, the FDA issued a ~~proposed~~ **final** rule to amend **and replace** the Quality System Regulation (QSR) **,** which ~~establishes~~ **sets forth the FDA' s** current ~~Good~~ **good** ~~Manufacturing~~ **manufacturing** ~~Practice~~ **practice** ~~(cGMP)~~ requirements for medical ~~device~~ **devices** ~~manufacturers~~, to align more closely with the International Organization for Standardization standards. **Specifically,** ~~This~~ **this** ~~proposal~~ **final rule, which the FDA expects to go into effect on February 2, 2026, establishes the " Quality Management System Regulation, " (QMSR) which among other things, incorporates by reference the quality management system requirements of ISO 13485: 2016. Although our quality management system is designed to comply with ISO 13485: 2016 in connection with our certifications outside of the United States, and although the FDA** has ~~not yet been finalized or adopted. Accordingly~~ **stated that the standards contained in ISO 13485: 216 are substantially similar to those set forth in the QSR**, it is unclear the extent to which this **final rule** ~~or any other proposals~~, ~~if adopted~~ **once effective**, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise ~~create competition that may~~ negatively affect our business **. If we are unable to comply with QMSR, once effective, or with any other changes in the laws or regulations enforced by FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition and results of operations**. Furthermore, the EU landscape concerning medical devices recently evolved. On May 26, 2021, the EU Medical Devices Regulation became applicable, and repealed and replaced the EU Medical Devices ~~Directive~~ **Directives** ~~and the Active Implantable Medical Devices Directive~~. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i. e., without the need for adoption of EU member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The EU Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. Our medical devices successfully obtained EU Medical Devices Regulation certification effective on January 31, 2023. We must now ensure continuous compliance with the new or reinforced requirements set forth in the EU Medical Devices Regulation. Non- compliance with said requirements may affect our business or the way we conduct our business in the EU. The aforementioned EU rules are generally applicable in the EEA. Non- compliance with the above requirements would also prevent us from selling our products in these three countries. ~~Senza is~~ **Our products are** 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 order to sell our products in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces EU Medical Devices ~~Directive~~ **Directives** ~~and the EU Active Implantable Medical Devices Directive~~. Compliance with these requirements is a prerequisite to be able to affix the European Conformity (CE) mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low ~~-~~ risk medical devices (Class I), where the manufacturer can self- assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with

applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. Following a national referendum and enactment of legislation by the government of the United Kingdom (UK), the UK formally withdrew from the EU and ratified a trade and cooperation agreement governing its relationship with the EU. The EU – UK Trade and Cooperation Agreement (TCA) was applied provisionally as of January 1, 2021 and entered into force on May 1, 2021. The TCA does not specifically refer to medical devices, but does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the " rules of origin " criteria will need to be reviewed. Depending on which countries products will be ultimately sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in Great Britain. On June 26, 2022, the MHRA published its response to a 10- week consultation on the post- Brexit regulatory framework for medical devices and diagnostics. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but have recently been postponed to July ~~2024~~ **2025** . In order to continue to sell Senza in the EU and UK, we must maintain our certification and continue to comply with EU legislation and also the UK legislation. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EU member states or the MHRA, could result in enforcement actions against us, including refusal, suspension or withdrawal of our certificates issued by our notified bodies, which could impair our ability to market products in the Europe in the future. In addition, we are subject to the EU General Data Protection Regulation (GDPR), which imposes obligations on companies that operate in our industry with respect to the processing of personal data of individuals within the EEA and the cross- border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to 20 million Euros or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. **Among** ~~Data privacy laws in the~~ **other requirements** ~~EU are developing rapidly and~~ , ~~in July 2020,~~ the **GDPR regulates** ~~Court of Justice of the EU limited how organizations could lawfully transfer~~ **transfers of** personal data **subject** ~~from the EEA~~ to **the GDPR to third countries that have not been found to provide adequate protection to such personal data, including** the United States **,** ~~by invalidating the Privacy Shield~~ and ~~imposing further restrictions~~ **the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union (CJEU) states that reliance** on ~~use of~~ the **standard** contractual clauses ~~, which could increase our costs~~ **- a standard form of contract approved by the European Commission as** ~~and~~ - **an adequate** ~~our ability to efficiently process~~ personal data **transfer mechanism- alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case- by- case basis. On October 7, 2022, President Biden signed an Executive Order on ' Enhancing Safeguards for United States Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers** from the EEA ~~. In March 2022, the US and EU announced a new regulatory regime intended~~ to ~~replace~~ the ~~invalidated regulations; however, this~~ **United States and which formed the basis of the** new EU- US Data Privacy Framework **(DPF),** ~~has~~ - **as released** ~~not been implemented beyond an executive order signed by President Biden~~ on ~~October 7~~ **December 13** , 2022 **. The European Commission adopted its Adequacy Decision in relation to the DPF** on ~~Enhancing Safeguards~~ **July 10, 2023, rendering the DPF effective as a GDPR transfer mechanism to U. S. entities self- certified under the DPF. The DPF also introduced a new redress mechanism** for **EU citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in future. We currently rely on the EU standard contractual clauses and the UK Addendum to the EU standard contractual clauses and the UK International Data Transfer agreement and the DPF, as relevant, to transfer personal data outside the EEA and the UK, including to the** United States ~~Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16~~ , **with respect** ~~2020 have taken a restrictive approach~~ to **both intragroup and third party transfers. We expect the existing legal complexity and uncertainty regarding** international **personal** data transfers **to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames** . Further, from January 1, 2021, companies have had to comply with the GDPR and the GDPR as incorporated into the UK national law, with each regime having the ability to fine up to the greater of € 20 million / £ 17. 5 million or 4 % of global turnover **. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U. S. entities self- certified under the UK Extension to the DPF. In recent years, U. S. and European lawmakers and regulators have also expressed concern over electronic marketing and the use of third- party cookies, web beacons and similar technology for online behavioral advertising. In particular, recent European court and regulator decisions are driving increased attention to cookies and tracking technologies. If the trend of increasing enforcement by European regulators of the strict approach to opt- in consent for all but essential use cases, as seen in recent guidance and decisions continues, this could lead to substantial costs, require significant systems changes, limit the effectiveness of our marketing activities, divert the attention of our technology personnel, adversely affect our margins, and subject us to additional liabilities. In light of the complex and evolving nature of EU, EU Member State and UK privacy laws on cookies and tracking technologies, there can be no assurances**

that we will be successful in our efforts to comply with such laws; violations of such laws could result in regulatory investigations, fines, orders to cease / change our use of such technologies, as well as civil claims including class actions, and reputational damage. Use of artificial intelligence is also increasingly being regulated. On April 21, 2021, the European Commission proposed a regulation seeking to establish a comprehensive, risk- based governance framework for artificial intelligence in the EU market (EU AI Act). The proposal is intended to apply to companies that develop, use and / or provide artificial intelligence in the EU and includes requirements around transparency, conformity assessments and monitoring, risk assessments, human oversight, security and accuracy, and proposes fines for breach of up to 6 % of worldwide annual turnover. In addition, on September 28, 2022, the European Commission proposed two Directives seeking to establish a harmonized civil liability regime for artificial intelligence in the EU, in order to facilitate civil claims in respect of harm caused by artificial intelligence and to include artificial intelligence- enabled products within the scope of the EU' s existing strict liability regime. These regulatory proposals are at varying stages of the legislative process and are not yet finalized; the EU AI Act is at an advanced stage and the text is currently expected to be finalized by the end of 2023. Once finalized and in force, this regulatory framework is expected to have a material impact on the way artificial intelligence is regulated in the EU, and together with developing guidance and / or decisions in this area, may affect our use of artificial intelligence and our ability to provide, improve or commercialize our services, require additional compliance measures and changes to our operations and processes, result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, operations and financial condition . In the EU, according to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. We are also subject to Directive 2006 / 114 / EC concerning misleading and comparative advertising, and Directive 2005 / 29 / EC on unfair commercial practices, as well as other EU member state legislation governing the advertising and promotion of medical devices. EU 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 and may impose limitations on our promotional activities with healthcare professionals. The aforementioned EU rules are generally applicable in the EEA. Non- compliance with the above requirements would also affect our business in these three countries. The misuse or off- label use of our product 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. ~~Senza has been approved for marketing in the United States, certified in the EU and approved by the TGA in Australia for specific treatments and anatomies.~~ We may only promote or market **our products** ~~the Senza SCS system~~ for ~~its~~ **their** specifically approved indications as described on ~~the~~ **their respective** approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as " off- label uses. " We cannot, however, prevent a physician from using our product off- label, when in the physician' s independent professional medical judgement he or she deems the use of the product in the non- approved indication as appropriate. There may be increased risk of injury to patients if physicians attempt to use our product off- label. Furthermore, the use of our product for indications other than those approved or certified by the applicable regulatory authority or notified body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Physicians 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 the FDA or foreign regulatory authorities determines that our promotional materials, training or physician support activities constitute promotion of an off- label use, it could request that we modify our training, promotional materials or physician support activities 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, regulators or legislators may also enhance the enforcement of, and attempt to curtail, any off- label use by physicians of medical devices in the future. Any of these events could significantly harm our business and results of operations and cause our stock price to decline. 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, competent authorities of the EU member states and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of 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 adverse health consequences or death. Manufacturers may, under their own initiative, conduct a product notification or recall to inform physicians of changes to instructions for use, or if a deficiency in a device is found or suspected. A government- mandated recall 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 issues. Recalls, which include certain notifications and corrections as well as removals, of ~~Senza~~ **our products** could divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation with customers, and reduce our ability to achieve expected revenue. In addition, the manufacturing of our products is subject to extensive post- market regulation by the FDA and foreign regulatory authorities, and any failure by us or our contract manufacturers or suppliers to comply with regulatory requirements could result in recalls, facility closures, and other penalties. We and our suppliers and contract manufacturers are subject to the QSR, and comparable foreign regulations which govern the

methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, and servicing of medical devices. These regulations are enforced through periodic inspections or audits of manufacturing facilities. Any manufacturing issues at our or our suppliers' or contract manufacturers' facilities, including failure to comply with regulatory requirements, may result in warning or untitled letters, manufacturing restrictions, voluntary or mandatory recalls or corrections, fines, withdrawals of regulatory clearances, approvals or certifications, product seizures, injunctions, or the imposition of civil or criminal penalties, which would adversely affect our business results and prospects. 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 medical device reporting 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 EU are legally bound to report serious incidents and Field Safety Corrective Actions (FSCAs) involving devices they produce or sell to the relevant authorities of the EU member states, in whose jurisdiction the incident occurred. 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. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us. The FDA and similar foreign governmental authorities such as the relevant authorities of the EU member states have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. 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 an unacceptable risk to health, 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 reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. We may be subject to federal, state and foreign healthcare ~~and ,~~ data privacy **,** and security 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, as well as data privacy and security laws and regulations ~~that govern the collection, use, disclosure and protection of personal information, including health-related information~~ , 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~~ **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 ~~;~~ **.** • ~~federal~~ **Federal** civil and criminal false claims laws, including the False Claims Act, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. In addition, 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 ~~;~~ **.** • Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters submitted for payment. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation ~~;~~ **.** • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements ~~;~~ **.** • ~~the~~ **The** federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U. S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members ~~;~~ **.** • ~~state~~ **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 companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA **.** ~~; and~~ • ~~federal~~ **Federal** and state laws and regulations governing the collection, use, disclosure and protection of health- related and other personal information that could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations ~~(e. g. Section 5 of the FTC Act)~~, that govern the collection, use, disclosure, and protection of health- related and other personal information. For example, the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023 and significantly amends the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also ~~creates~~ **created** a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. The CCPA and the CPRA may increase our compliance costs and potential liability. Similar laws have been passed in ~~Virginia~~ **other states** , ~~Utah, Connecticut~~ and ~~Colorado and~~ **are continuing to be** proposed at the federal level and in other states. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. **• Section 5 (a) of the Federal Trade Commission Act (FTC) Act. The FTC has authority to initiate enforcement actions against entities that fail to limit third- party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5 (a) of the FTC Act. According to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Additionally, federal and state consumer protection laws are increasingly being applied by the FTC and states' attorneys general to regulate the collection, use, storage, and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content. • Foreign data privacy and security laws. Please see " Risk Factors- Senza is 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 " for more information.** The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have 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. ~~We~~ **For example, we** received a Civil Investigative Demand in December 2022 related to the marketing, promotion and billing practices of the Company' s SCS system. Responding to investigations can be time- and resource-consuming and can divert management' s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. If our operations are 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 **. The regulatory framework for machine learning technology, artificial intelligence and automated decision making is evolving and our failure to comply with such laws and regulations could have a material adverse effect on our business. We may not always be able to anticipate how to respond to laws or regulations around machine learning technology, artificial intelligence and automated decision making given they are still rapidly evolving. There is an increase in litigation in a number of jurisdictions, including the United States, relating to the use of artificial intelligence. New laws regulating artificial intelligence are at an advanced stage of the legislative process in the EU, and it is possible that new laws and regulations will be adopted in the United States and in other non- U. S. jurisdictions, or that existing laws and regulations may be interpreted in ways that would affect the operation of our learning platforms, online testing business and data analytics and the way in which we use artificial intelligence and machine learning technology. Further, the cost to comply with such laws or regulations, or decisions and / or guidance interpreting existing laws, could be significant and would increase our operating expenses, which could adversely affect our business, financial condition and results of operations. Please see " Risk Factors- Senza is 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 " for more on**

developing regulations around use of artificial intelligence in the EU . 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. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers ~~of 2 % per fiscal year~~ , which went into effect on April 1, 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 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 (MACRA), 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, federal and foreign healthcare reform measures will be adopted in the future. 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 demand for our product or result in additional pricing pressures. For instance, on December 13, 2021, Regulation No 2021 / 2282 on Health Technology Assessment **(HTA)** , amending Directive 2011 / 24 / EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once ~~the Regulation becomes~~ applicable, it will have a phased implementation depending on the concerned products. ~~This~~ **The** ~~regulation~~ **Regulation** intends to boost cooperation among EU member states in assessing health technologies, including certain high- risk medical devices, and ~~providing~~ **provide** the basis for cooperation at the EU level for joint clinical assessments in these areas. **It** ~~The regulation~~ will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the ~~most~~ **highest** potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. Our future success depends on our ability to develop, receive regulatory clearance, approval or certification for, additional chronic pain indications for ~~Senza~~ **our products** 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 chronic pain. As such, our success will depend in part on our ability to expand the chronic pain indications for which our products may be used and / or develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance, approval or certification for expanded indications or 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, approvals or certifications 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. Risks Related to Our Securities Our stock price has experienced significant volatility and may continue to be volatile. As a result, our stockholders may not be able to resell shares of our common stock at or above the price they paid ~~and .~~ ~~such~~ **Such** volatility may also adversely impact the value of the 2025 Notes **and Braidwell Warrants** . The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this " Risk Factors " section of this Annual Report and others such as: • achievement of expected product sales and profitability, including the effects of seasonality on our results of operations, as well as adjustments to our sales forecasts; • ~~the ongoing COVID- 19 pandemic, see " — Risks Related to our Business — Our business, financial condition, results of operations and growth could be harmed by the effects of the COVID- 19 pandemic "; •~~ delays or setbacks in the commercialization of ~~Senza~~ **our products** or the expansion of indications for which ~~Senza is~~ **our products are** approved; • announcements of new products by us or our competitors; • announcements or developments in any intellectual property infringement actions in which we may become involved ~~, including our lawsuits with Boston Scientific~~ ; • manufacture, supply or distribution shortages; • adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply

chain or sales and marketing activities; • our operating results; • results from, or any delays in, clinical trial programs relating to our product candidates; • 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; • announcements concerning our competitors or the medical device industry in general; • actual or anticipated fluctuations in our operating results; • FDA or other U. S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the United States; • changes in financial estimates or recommendations by securities analysts, as well as publications from research analysts associated with short selling; • trading volume of our common stock; • trading activity in our common stock by the option counterparties to our convertible note hedge transactions to unwind or modify their hedge positions; • sales of our common stock by us, our executive officers and directors or our stockholders in the future; • general economic and market conditions and overall fluctuations in the United States equity markets, including as a result of volatility related to the recent coronavirus outbreak and related health concerns; and • the loss of any of our key management personnel. Because the 2025 Notes **and Braidwell Warrants** are convertible into shares of common stock, volatility or depressed market prices of our common stock could have a similar effect on the value of the 2025 Notes **and / or Braidwell Warrants** . Holders who receive shares of our common stock upon conversion of the 2025 Notes **and / or the Braidwell Warrants** will also be subject to the risk of volatility and depressed market prices of our common stock. Similarly, the liquidity of the trading market in the 2025 Notes **and / or Braidwell Warrants** , and the market price quoted for the 2025 Notes **and / or Braidwell Warrants** , may be adversely affected by changes in the overall market for ~~this~~ **these** ~~type~~ **types** of security and by changes in our financial performance or prospects or in the prospects for companies in our industry generally. In addition, the stock markets in general, and the markets for medical device stocks in particular, have experienced volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock and the value of the 2025 Notes **and / or Braidwell Warrants** . 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. Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the 2025 Notes **and the Braidwell Term Loans** , or to make cash payments in connection with any conversion of the 2025 Notes **or payments due for the Braidwell Term Loans** , depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. **The terms** ~~Regulatory actions and other events may adversely affect the value and liquidity~~ of ~~the 2025 Notes. We expect that~~ **our credit facility place restrictions on our operating and financial flexibility, and we** ~~many~~ **may** ~~investors~~ **not have cash available to us** in ~~, and~~ **an** ~~potential purchasers of, the 2025 Notes will employ,~~ **amount sufficient to enable us to make interest or principal payments on** ~~or~~ **our indebtedness when due. In November** ~~seek to employ, a convertible arbitrage strategy with respect to the 2025~~ **2023** ~~Notes~~ **, we entered into the Braidwell Credit Agreement** . ~~Investors would typically implement such a strategy~~ **All obligations under the Braidwell Credit Agreement are secured** by **substantially all** ~~selling short the common stock underlying the notes and dynamically adjusting their short position while continuing to hold the 2025 Notes. Investors may also implement this type~~ of ~~strategy by entering into swaps on our common stock in lieu of or~~ **our existing property** ~~in addition to short selling the common stock. The SEC~~ and **assets** ~~other regulatory and self- regulatory authorities have implemented various rules and taken certain actions, and may in the future adopt additional rules and take other actions, that may impact those engaging in short selling activity involving equity securities~~ (including our ~~common~~ **intellectual property assets), subject to certain exceptions. This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. The Braidwell Credit Agreement includes representations and warranties and covenants, including affirmative covenants and negative covenants that restrict our and our subsidiaries' ability to, among other things, incur indebtedness, grant liens, merge or consolidate, make investments, dispose of assets, make acquisitions, pay dividends or make distributions, repurchase** stock ~~). Such rules~~ and ~~actions include Rule 201 of SEC Regulation SHO, the adoption by the Financial Industry Regulatory Authority, Inc., or FINRA, and the national securities exchanges of a " Limit Up- Limit Down " program, the imposition of market- wide circuit breakers that halt trading of securities for certain periods following specific market declines, and the implementation of certain regulatory reforms required by the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010. Any governmental or regulatory action that restricts the ability of investors in, or potential purchasers of, the notes to effect short sales of our common stock, borrow our common stock or~~ enter into ~~swaps~~ **certain transactions with affiliates, in each case subject to certain exceptions. The Braidwell Credit Agreement also has a financial covenant requiring us and our subsidiaries to maintain, as of the last day of each fiscal quarter ending after the Closing Date (as defined in the Braidwell Credit Agreement), at least $ 300. 0 million in trailing twelve month revenue; provided that a failure of the us and our subsidiaries to maintain such minimum revenue shall not be an event of default under the Braidwell Credit Agreement unless such failure continues for three consecutive fiscal quarters, so long as we and our subsidiaries maintain at least $ 75. 0 million of liquidity at all times starting from the first day after the first fiscal quarter in which**

the foregoing financial covenant is not met and ending on **the date we deliver a certificate to the administrative agent under the Braidwell Credit Agreement evidencing compliance with the foregoing financial covenant. The Braidwell Credit Agreement also contains customary events of default, including among other things, our failure to make any principal** ~~our~~ **or** ~~common stock~~ **interest payments when due, the occurrence of certain bankruptcy or insolvency events, or our breach of the covenants under the Braidwell Credit Agreement. Upon the occurrence of an event of default, the lenders thereunder may, among other things, accelerate our obligations under the Braidwell Credit Agreement. As security for our obligations under the Braidwell Credit Agreement, we and our subsidiary Nevro Medical CR, LLC granted the agent (for the benefit of the secured parties) a continuing security interest in substantially all of our assets (including intellectual property), subject to certain customary exceptions. Failure to satisfy our current and future debt obligations, including covenants to take or avoid specific actions, under the Braidwell Credit Agreement** could **result in** ~~adversely affect the trading price and~~ **an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Braidwell Credit Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness while still pursuing our current business strategy. In addition, our lenders could seek to enforce** ~~the~~ **their** ~~liquidity of the 2025 Notes~~ **security interests in any collateral securing such indebtedness**. We may incur substantially more debt or take other actions which would intensify the risks discussed above. We and our subsidiaries may incur substantial additional debt in the future, subject to the restrictions contained in any debt instruments we may have, some of which debt may be secured debt ~~. We are not restricted under the terms of the indenture governing the 2025 Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the 2025 Notes that could have the effect of diminishing our ability to make payments on these notes when due~~. If we are unable to maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock and the value of the 2025 Notes **and / or Braidwell Warrants** could be adversely affected. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. Further, the Sarbanes- Oxley Act also requires that our internal control over financial reporting be attested to by our independent registered public accounting firm. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. The process of designing and implementing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our **public securities** ~~common stock and the value of the 2025 Notes~~ 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 ~~. The accounting method for convertible debt securities that may be settled in cash, such as the 2025 Notes, could have a material effect on our reported financial results. Under Accounting Standards Codification 470- 20, Debt with Conversion and Other Options (ASC 470- 20), an entity must separately account for the liability and equity components of the convertible debt instruments (such as the 2025 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer' s economic interest cost. The effect of ASC 470- 20 on the accounting for the 2025 Notes is that the equity component is required to be included in the additional paid- in capital section of stockholders' equity on our consolidated balance sheet, and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the 2025 Notes. As a result, we will be required to record a greater amount of non- cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the 2025 Notes to their face amount over the respective terms of the 2025 Notes. We will report lower net income (or larger net losses) in our financial results because ASC 470- 20 will require interest to include both the current period' s amortization of the debt discount and the instrument' s non- convertible interest rate, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the notes. In addition, under certain circumstances, convertible debt instruments (such as the 2025 Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the 2025 Notes are not included in the calculation of diluted earnings per share except to the extent that the respective conversion values of the 2025 Notes exceeds their respective principal amounts. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. In August 2020, the FASB issued a new standard that proposes to change the accounting for the convertible debt instruments described above. Under the new standard, an entity may no longer be required to separately account for the liability and equity components of convertible debt instruments. This could have the impact of reducing non- cash interest expense, and thereby increasing net income (or decreasing net losses). Additionally, the treasury stock method for calculating earnings per share will no longer be allowed for convertible debt instruments whose principal amount may be settled using shares. Rather, the if- converted method may be required, which could decrease our diluted earnings per share. The new standard is effective for fiscal years beginning after December 15, 2021 and interim periods within that year, with early adoption permitted, and can either be adopted on a modified retrospective or full retrospective basis~~. If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price and the

value of the 2025 Notes may decline. We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price ~~and the value of the 2025 Notes~~ may decline. Sales of a substantial number of shares of our common stock in the public market could cause our stock price and the value of ~~the 2025 Notes~~ **our public securities** to fall. In the future, we may sell additional shares of our common stock to raise capital. In addition, a substantial number of shares of our common stock is reserved for issuance upon the exercise of stock options, upon the vesting of restricted stock units, upon conversion of the 2025 Notes, upon exercise of the warrants in the warrant transactions we entered into in connection with the offering of the ~~2021 Notes and~~ 2025 Notes **and the Braidwell Warrants** . We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance and sale of substantial amounts of common stock, or the perception that such issuances and sales may occur, could adversely affect the trading price of the notes and the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. 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 and the value of ~~the 2025 Notes~~ **our public securities** could decline. As of December 31, ~~2022~~ **2023** , we had outstanding a total of approximately ~~35~~ **36** . ~~5~~ **4** million shares of common stock, and approximately ~~10~~ **11** . ~~3~~ **2** million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock and the value of the ~~2025 Notes~~ **our public securities** could decline. 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 amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that: • we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person' s conduct was unlawful; • we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law; • we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification; • we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification; • the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and • we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents. We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their 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. **In addition, the terms of any of our existing, and potentially future, debt or credit agreements will restrict or preclude us from paying dividends. For example, under the Braidwell Credit Agreement, we are restricted from paying any dividends or making any distributions on account of our capital stock subject to certain exceptions set forth in the Braidwell Credit Agreement.** Therefore, our stockholders are not likely to receive any dividends on our common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our stockholders have purchased it. General Risk Factors Changes in tax laws, tax rulings or trade policies may have a material adverse effect on our business, financial condition and results of operations. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. The tax regimes we are subject to or operate under, including income and non- income taxes, are unsettled and may be subject to significant change. Changes in tax laws or tax rulings, or changes in interpretations of existing laws, could materially affect our financial position, results of operations, and cash flows. Recently enacted legislation and associated regulations have significantly changed U. S. federal income tax laws, with potential impact to state and local taxation. Further, many countries in Europe have recently proposed or recommended changes to existing tax laws or have enacted new laws that may increase our tax obligations in those countries. In addition, changes in U. S. trade policies could materially and adversely impact our effective tax rate, increase our costs and reduce the competitiveness of our products. Failure to protect our information technology infrastructure, and those of our third- party service providers, against cyberattacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results. We **collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store**

and transmit large amounts of confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data, health- related information and personal information of our customers, employees and other related third parties (collectively, Confidential Information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We rely on information technology and telephone networks and systems, including the Internet, to process and transmit **Confidential** ~~sensitive electronic information~~ **Information** and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement and supply chain, manufacturing and distribution. We 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, may be susceptible to damage, disruptions or shutdowns due to computer viruses and malware (e. g. ransomware), **misconfigurations, " bugs " or other vulnerabilities,** " phishing " attacks and other social engineering schemes, attacks by computer hackers, natural disasters, terrorism, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, human error, catastrophic events, fraud, denial or degradation of service attacks, sophisticated nation- state and nation- state- supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the ~~COVID- 19 pandemic~~ **continued hybrid working environment** , we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems 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. **There can also be no assurance that our, our programs', and our CROs', contractors, consultants' and collaborators' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.** We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur, it could result in a material disruption of our business operations, whether due to a loss, corruption or unauthorized disclosure of our **Confidential** ~~trade secrets, personal information~~ **Information** ~~or other proprietary or sensitive information~~ or other similar disruptions. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of ~~personal~~ **Confidential** ~~information~~ **Information** , it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. Any security compromise affecting us, our service providers, strategic partners, other contractors, consultants, or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business. We may not be able to adequately protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of

being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and if we do prevail, 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 that are the same as or similar to our products, and our competitive position in the international market would be harmed. 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 registered trademarks similar and identical to our trademarks in foreign jurisdictions, and 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 were 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 securities or industry analysts 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 publish about us or our business. If any of the analysts who cover us issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. For example, in the fourth quarter of 2020, a research analyst associated with short selling activity published a report that resulted in short term volatility in our stock. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. We incur significantly increased costs and devote substantial management time as a result of operating as a public company. As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of the Exchange Act, and are required to comply with the applicable requirements of the Sarbanes- Oxley Act of 2002 (Sarbanes- Oxley Act), and the Dodd- Frank Act, as well as rules and regulations subsequently implemented by the SEC and the NYSE, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, our management and other personnel divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes- Oxley Act. We continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We cannot predict or estimate the amount of additional costs we will incur in order to remain compliant with our public company reporting requirements or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability.