Risk Factors Comparison 2025-02-18 to 2024-02-09 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our reputation, business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Risks related to our business We have a history of significant losses, which we expect to continue, and we may not be able to achieve or sustain profitability. If we do not achieve and sustain profitability, our financial condition could suffer. We have experienced significant net losses since our inception and we expect to continue to incur losses for the foreseeable future. We incurred net losses of $ ~~41~~ **60** . ~~2~~ **0** million and $ 41. ~~4~~ **2** million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. As of December 31, **2024 and** 2023 ~~and 2022~~ , our accumulated deficit was $ **537. 3 million and $** 477. 4 ~~million and $ 436. 2~~ million, respectively. We expect to continue to incur significant sales and marketing, research and development, regulatory **,** and other expenses as we grow our U. S. commercial sales force and expand our marketing efforts to increase adoption of Barostim, add new features to Barostim, obtain regulatory clearances or approvals for our planned or future products and conduct clinical trials on our existing and planned or future products. ~~Until our IPO, we financed our operations primarily through convertible preferred stock financings and amounts borrowed under our previous loan and security agreement (" Horizon loan agreement ") with HorizonTechnology Finance Corporation. We had devoted substantially all of our financial resources to research and development activities as well as general and administrative expenses associated with our operations, including clinical and regulatory initiatives to obtain marketing approval. Since our IPO, we have invested substantially in sales and marketing efforts to support commercialization of Barostim.~~ We will need to continue to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations. We have a limited history operating as a commercial company and are highly dependent on a single product, Barostim. The failure to increase market acceptance in the U. S. for Barostim would negatively impact our business, liquidity **,** and results of operations. We first commercialized Barostim in the EEA in 2012 and in the U. S. in 2020 and therefore do not have a long history operating as a commercial company. We expect substantially all of our revenue to continue to be derived from sales of Barostim for the foreseeable future, the majority of which will be generated in the U. S. Although increasing as our commercial sales grow, Barostim still has limited product and brand recognition. In addition, demand for Barostim may decline or may not continue to increase as quickly as we expect. If we are unable to achieve significant market acceptance in the U. S. for Barostim, our results of operations will be adversely affected. Because we do not yet have other products currently in development, if we are unsuccessful in commercializing Barostim or are unable to market Barostim as a result of a quality problem, failure to maintain regulatory approvals, unexpected or serious complications or other unforeseen negative effects related to Barostim or the other factors discussed in these risk factors, we would lose our main source of revenue, and our business, reputation, liquidity and results of operations will be materially and adversely affected. We have limited commercial sales experience marketing and selling Barostim, and if we are unable to continue to maintain and grow sales and marketing capabilities, we will be unable to generate sustained and increasing product revenue. In order to generate future revenue growth, we plan to continue to expand the size and geographic scope of our U. S. direct sales and marketing organization. In order to increase our sales and marketing efforts, we will need to continue to retain, grow and develop a substantial number of direct sales personnel, which is a significant investment. 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 product will often require or benefit from direct support from us. If we are unable to attract, motivate, develop **,** and retain a sufficient number of qualified sales personnel, and if our sales 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. Because the competition for direct medical sales personnel is high, we cannot be certain we will be able to hire and retain additional sales personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating anticipated revenue. Any of these risks may adversely affect our business. We must demonstrate to physicians and patients the merits of Barostim. Physicians play a significant role in determining the course of a patient' s treatment and, subsequently, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing Barostim to physicians. In order for us to sell Barostim, we must successfully demonstrate to physicians and patients the merits of Barostim Therapy for use in treating patients with HFrEF. Specifically, Barostim is indicated for patients with NYHA Class III or II (with recent history of III) despite treatment with guideline- directed medical therapies (medications and devices), have a LVEF ≤ 35 % ~~42and~~ -- **and** a NT- proBNP < 1, 600 pg / ml. Barostim delivers **BAT** ~~Baroreflex Activation Therapy~~ to improve patients'

NYHA functional status, 6MHW and quality of life. Acceptance of Barostim depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost- effectiveness of Barostim and communicating to physicians the proper application of Barostim Therapy for patients who meet Barostim' s eligibility criteria. If we are not successful in convincing physicians of the merits of Barostim Therapy, they may not use Barostim and we may be unable to increase our sales, sustain our growth or achieve profitability. In addition, physicians typically need to perform several procedures to become comfortable using Barostim. 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. It is critical to the success of our commercialization efforts to educate physicians on the proper use of Barostim, and to provide them with adequate product support during clinical procedures. If we do not provide support to physicians or do not adequately educate physicians on the benefits and proper use of Barostim, physicians may not use or advocate for Barostim. In such circumstances, our results of operations would be materially adversely affected. Patients may not choose or be able to receive Barostim if, among other potential reasons, they are reluctant to receive an implantable device as opposed to an alternative, non- implantable treatment, they are worried about potential adverse effects of Barostim, or they are unable to obtain adequate third- party coverage or reimbursement. ~~Our~~ **42Our** industry is highly competitive. If our competitors, many of which are large, well-established companies with substantially greater resources than us and have a long history of competing in the HF market, are better able to develop and market products that are safer, more effective, less costly, easier to use **,** or otherwise more attractive than Barostim, 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 market by securing broad market acceptance of Barostim Therapy and Barostim for the treatment of HFrEF. Any product we develop that achieves regulatory clearance or approval, including Barostim, will have to compete for market acceptance and market share **against other therapies, including both devices and medications** . We believe that the primary competitive factors in the market are demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects and salesforce experience. Many of our current and potential competitors that are addressing other HF indications are publicly traded, or are divisions of publicly- traded, established medical device companies that have substantially greater financial, technical, sales and marketing resources than we do, such as Medtronic plc, Boston Scientific Corporation, Abbott Laboratories and ~~LivaNova PLC~~ **Johnson & Johnson** . We may also face competition from other competitors, such as Impulse Dynamics, which is a private company with a medical device indicated for a subset of our target patient population, or companies with active system development programs that may emerge in the future **, such as Johnson & Johnson' s interatrial shunt system (formerly V- Wave)** . Many of the companies developing or marketing competing products enjoy several advantages over us, including, among others: • more experienced sales forces; • greater name recognition; • more established sales and marketing programs and distribution networks; • earlier regulatory approval; • long established relationships with physicians and hospitals; • significant patent portfolios, including issued U. S. and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third- party suppliers and distributors; • the ability to acquire and integrate our competitors and / or their technology; • demonstrated ability to develop product enhancements and new product offerings; • established history of product reliability, safety **,** and durability; ~~43 -~~ • the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives; • greater financial and human resources for product development, sales **,** and marketing; and • greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products. Our competitors may develop and patent processes or products earlier than us, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products more rapidly than us or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. We also face fierce competition, particularly in this tight labor market, in recruiting and retaining qualified sales, scientific and management personnel, establishing clinical trial sites and enrolling patients in clinical studies. If our competitors are more successful than us in these matters, our business may be harmed. In addition, we face a particular challenge overcoming the long- standing practices by some physicians of using the products of our larger, more established potential competitors. Physicians who have completed many successful implants using the 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. ~~If~~ **43If** we fail to receive access to hospitals, our sales may decrease. In the U. S., in order for physicians to use Barostim, hospitals where these physicians treat patients typically require us to enter into purchasing contracts. This process can be lengthy, time- consuming and require extensive negotiations and management time, which could include an approval by a customer' s value analysis committee. In the EEA, 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, and we may not be successful in the bidding process. If we do not receive access to hospitals via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may 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 are dependent upon third- party manufacturers and suppliers, and in some cases a limited number of suppliers, making us vulnerable to supply shortages, loss or degradation in performance of the suppliers, price fluctuations **,** and ongoing supply chain disruptions, which could harm our business. We currently source certain components for Barostim from a limited number of suppliers. Our ability to supply Barostim commercially depends, in part, on our ability to obtain a supply of these components that has been manufactured in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We have not entered into manufacturing, supply **,** or quality agreements with some of our limited suppliers, some of which supply components critical to our products,

such as modules, batteries , and electrodes. We cannot guarantee that our suppliers will be able to meet our demand for their products and services, either because of the nature of our arrangements with those suppliers, our limited experience with those suppliers, or due to our relative importance as a customer to those suppliers. Further, due to our limited operating history and expected future expansion, it may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. 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 reliance on these third- party suppliers also subjects us to other risks that could harm our business, including, among others: • we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours; ~~44~~ • 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 an adequate supply of components in a timely manner or on commercially reasonable terms; • our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the effectiveness or safety of Barostim or cause delays in shipment; • we may have difficulty locating and qualifying alternative suppliers; • switching components or suppliers may require product redesign and possibly submission to the FDA, EEA , or other foreign regulatory bodies, which could significantly impede or delay our commercial activities; **•** one or more of our limited source suppliers may be unwilling or unable to supply components of Barostim; **44** • other customers may use fair or unfair negotiation tactics and / or pressures to impede our use of the supplier; • we do not conduct rigorous, formal environmental, social or governance due diligence on our supply chain and thus may not be aware if our suppliers pose such risks; • 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 **, geopolitical,** or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements. Establishing additional or replacement suppliers for the components or processes used in Barostim, if required, could be time- consuming and expensive. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the limited sourced 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. Given our reliance on certain limited source suppliers, we are especially susceptible to supply shortages because we have limited alternate suppliers currently available. Manufacturing risks may adversely affect our ability to manufacture our product and could reduce our gross margin and profitability. Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements , and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including: • quality or reliability defects in product components that we source from third- party suppliers, including manufacturing compliance with federal and state regulations; • our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms; • our failure to increase production of products to meet demand; • our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements; and • potential damage to or destruction of our manufacturing equipment or manufacturing facility. ~~45As~~ **As** demand for Barostim increases, we have invested, and expect to continue to invest, additional resources to purchase components, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our product candidates in development to share product features and components with Barostim, manufacturing of these product candidates may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these product candidates at a cost or in quantities sufficient to make these product candidates commercially viable. Any of these factors may affect our ability to manufacture our product and could reduce our gross margin and profitability. We operate at a facility in one location and any disruption at this facility could harm our business. Our principal offices and our only manufacturing facility are located in Minneapolis, Minnesota. Substantially all of our operations are conducted at this location, including our manufacturing processes, research, ~~development~~ **45development** and engineering activities, customer and technical support and management and administrative functions. In addition, substantially all of our inventory of component supplies and finished goods is held at the manufacturing facility. Vandalism, terrorism or a natural or other disaster, such as a fire or flood, could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information , and cause us to incur additional expenses **. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facility may harm our business, financial condition, and operating results** . Our manufacturing facility in Minneapolis, Minnesota is our only manufacturing facility, and if it is damaged or rendered inoperable or inaccessible due to political, social or economic upheaval or due to natural or other disasters, it would be difficult or impossible for us to manufacture our product for a period of time, which may lead to a loss of customers and significant impairment of our ~~financial condition and operating results. We take precautions to safeguard this facility, including acquiring insurance, employing back- up generators, adopting health and safety protocols and utilizing off- site storage of computer data. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facility may harm our business,~~ financial condition and operating results. Our international operations

subject us to certain operating risks, which could adversely impact our results of operations and financial condition. The sale and shipment of Barostim across international borders, as well as the purchase of components from international sources, subjects us to U. S. and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non- compliance. Other laws and regulations that can significantly impact us include various anti- bribery laws, including the FCPA, 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, among others: • 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; • potential pricing pressure; ~~46~~ • a shortage of high- quality sales representatives and distributors; • competitive disadvantage to competition with established business and customer relationships; • foreign currency exchange rate fluctuations; • the imposition of additional U. S. and foreign governmental controls or regulations; • economic instability; • changes in duties and tariffs, license obligations and other non- tariff barriers to trade; • the imposition of restrictions on the activities of foreign agents, representatives **,** and distributors; • scrutiny of U. S. and foreign tax authorities, which could result in significant fines, penalties and additional taxes being imposed on us; • laws and business practices favoring local companies; • longer payment cycles; • difficulties in maintaining consistency with our internal guidelines; • difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; **46** • 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; and • the imposition of new trade restrictions. If any of these risks are realized, our sales in non- U. S. jurisdictions may be adversely affected and our results of operations would suffer. Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell Barostim at prices necessary to support our current business strategies. Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third- party ~~payors~~ **payers** . Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for price concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third- party coverage ~~and~~ **, provider constraints,** reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our future customers, which may exert further downward pressure on the prices of Barostim. If we fail to properly manage our growth effectively, our business could suffer. We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, the hiring of our direct sales force requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. To achieve our revenue goals, we must continue to successfully increase manufacturing output to meet expected customer demand. We may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, **such as skilled operators who can assemble our product,** among other problems. Any of 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. ~~47Future~~ -- **Future** growth will continue to 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 may have an adverse effect on our business, financial condition **,** and results of operations. If clinical studies for future indications do not produce results necessary to support regulatory clearance or approval in the U. S. or elsewhere, we will be unable to commercialize our products for these indications. We will likely need to conduct additional clinical studies in the future to support approval for new indications. Clinical testing takes many years, is expensive and carries uncertain outcomes. The initiation and completion of studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following: **47** • the FDA, IRBs, ethics committees, EU competent authorities **,** 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; • 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 EEA member state or other foreign regulations governing clinical trials; • 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

results are inconclusive or unfavorable as to immediate and long- term safety or effectiveness; • regional or worldwide conditions, like an infectious disease or pandemic, precluding or interfering with execution; • the study design is inadequate to demonstrate safety and effectiveness; or • the statistical endpoints are not met. Clinical trials can fail at any stage. 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. In addition, if the FDA determines for any reason, including safety or their risk- benefit analysis, that the results of a trial are negative, the FDA may decide to modify or revoke our existing ~~48approval --~~ **approval** or such data may impact the adoption of Barostim. Moreover, a negative perception of clinical results for one indication for use could impact the use of Barostim for other FDA approved and clinically supported indications for use. We could also encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized. Even if our products are approved in the U. S. and the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U. S. or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition **,** and prospects significantly. ~~We~~ **48We** may face product liability claims that could be costly, divert management' s attention and harm our reputation. Manufacturing and marketing of Barostim and clinical testing of Barostim Therapy may expose us to product liability claims. The coverage limits of our liability 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. Further, interpretation of product liability laws may change in the future due to court rulings. It is possible evolving interpretations of product liability laws could further expose us to increased litigation risk in connection with our products. These product liability claims could, among other things, divert management' s attention from our primary business and negatively affect our reputation, continued product sales and our ability to obtain and maintain regulatory approval for our products. If we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely affected while we attract other highly qualified personnel. Our future success depends, in part, on our ability to continue to retain our executive officers and other key employees and recruit and hire new employees. All of our executive officers and other employees are at- will employees, and therefore may terminate employment with us at any time with no advance notice. In particular, we are highly dependent upon our management team, especially our President and Chief Executive Officer and the rest of our senior management. The replacement of key personnel involves significant time and costs, may significantly delay or prevent the achievement of our business objectives and may harm our business. In addition, we do not carry any " key person " insurance policies that could offset potential loss of service under applicable circumstances. **Transitions in executive leadership can adversely affect relationships with our customers, suppliers, and employees, make it difficult to attract and retain talent, and disrupt execution of our strategy, sales growth, and our efforts to enhance our operations. Additionally, such transitions can require significant payments to recruit and attract qualified employees to join our company and may involve severance payments to certain departing employees. Changes in key management positions may temporarily affect our financial performance and results of operations as the new management becomes familiar with our business and establishes their team dynamic. For example, in February 2024, we appointed a new Chief Executive Officer who replaced our prior Chief Executive Officer, who had been in the role for 17 years. We experienced some disruption within the sales organization at the time of the Chief Executive Officer transition, which led to decreased productivity and higher salesforce turnover, as well as the termination of employment of our Senior Vice President of U. S. Sales. Since the beginning of the second quarter of fiscal 2024, we have hired new leaders for sales, medical affairs, clinical, reimbursement and human resources, completing the expansion of the executive team. Accordingly, our future financial performance will depend on our ability to attract, motivate, integrate, and retain our senior management and employees, and effectively manage this period of transition under our new leadership.** In addition, many of our employees have become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Although non- compete agreements are becoming more disfavored and, in some cases, banned, many executive officers and employees in the medical device industry are still subject to strict non- compete or confidentiality agreements with their employers. In addition, some of our existing and future employees are subject to confidentiality agreements with previous employers. Our competitors may allege breaches of and seek to enforce such non- compete agreements or initiate litigation based on such confidentiality agreements. ~~49Such --~~ **Such** litigation, whether or not meritorious, may impede our ability to attract or use executive officers and other key employees who have been employed by our competitors and may result in claims against us. ~~Failure~~ **49Failure** to protect our information technology infrastructure against cyber- based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results. We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement **,** and supply chain, manufacturing **,** and distribution. We 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, attacks by computer hackers, failures during the process of upgrading or replacing software, databases , or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. 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. If important assumptions about the potential market for our product are inaccurate, or if we have failed to understand what people with HF are seeking in a treatment, we may not be able to increase our revenue or achieve profitability. Our business strategy was developed based on a number of important assumptions about the HF market in general, any one or more of which may prove to be inaccurate. For example, we believe that the benefits of Barostim as compared to other common HF devices will continue to drive growth in the market for Barostim. Despite our review of studies reporting on the trends of HF incidence in the U. S., the actual incidence of HF and the actual demand for our product or competitive products could differ materially from our expectations. In addition, our strategy of focusing exclusively on patients with HFrEF who are looking for an improvement in the symptoms associated with HFrEF may limit our ability to increase sales or achieve profitability, especially if there are any significant clinical breakthroughs or product or drug introductions that significantly delay or reduce the need for heart disease therapy. Moreover, a percentage of our indicated patients may be ineligible to undergo a Barostim procedure if they have certain co- morbidities or other disqualifying factors as determined by their physicians. Our estimates of the annual total addressable market for Barostim are based on a number of internal and third- party estimates, including, without limitation, the number of patients with HFrEF and the assumed prices at which we can sell our device. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for Barostim may prove to be incorrect. If the actual number of patients who would benefit from our product, the price at which we can sell our product, or the annual total addressable market for our product is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. Unfavorable economic conditions could adversely affect our business, financial condition , or results of operations. Our results of operations could be adversely affected by general conditions in the economy and the financial markets. Concerns over economic and political stability, inflation levels and related efforts to mitigate inflation, a potential recession, the level of U. S. national debt, currency fluctuations and volatility, the rate of growth of Japan, China and other Asian economies, unemployment, the availability and cost of credit, trade relations, including the imposition of various sanctions and tariffs, infectious diseases or pandemics, climate- related events, energy costs and geopolitical uncertainty and conflict have contributed to increased volatility and diminished expectations for the economy and markets in general. An economic downturn could result in a ~~50variety~~ **variety** of risks to our business, including weakened demand for Barostim and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers or suppliers, resulting in supply disruption, or causing our customers to delay making ~~payments~~ **50payments** for our services. Certain of the foregoing have harmed and could in the future harm our business, and we cannot anticipate all of the ways in which the economic climate and financial market conditions may further affect our business. We may enter into strategic collaborations, in- licensing arrangements , or alliances with third parties that may not result in the development of commercially viable products or the generation of significant future revenue. In the ordinary course of our business, we may enter into strategic collaborations, in- licensing arrangements , or alliances to develop product candidates and to pursue new markets. Proposing, negotiating , and implementing strategic collaborations, in- licensing arrangements or alliances may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology , or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure , or complete any such transactions or arrangements in a timely manner, on a cost- effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenue and could be terminated prior to developing any products. Additionally, we may not be in a position to exercise sole decision- making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could impair our ability to execute our business strategies. From time to time, we may consider opportunities to acquire other products or technologies that may enhance our Barostim platform technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including, among others: • problems assimilating the acquired products or technologies; • issues maintaining uniform standards, procedures, controls , and policies; • unanticipated costs associated with acquisitions; • diversion of management' s attention from our existing business; • risks associated with entering new markets in which we have limited or no experience; and • increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters. We have no current commitments with respect to any acquisition. We do not know if we will be able to

identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our inability to integrate any acquired products or technologies effectively could impair our ~~51ability --~~ **ability** to execute our business strategies. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses. ~~If~~ **51If** third- party ~~payors~~ **payers** do not provide adequate coverage and reimbursement for the use of Barostim, our revenue will be negatively impacted. Medicare reimbursement levels are important to increasing adoption of Barostim **and establishing Barostim as the standard of care** because nearly two- thirds of the target patient population for Barostim is over the age of 65. ~~In the~~ **On January 1,** 2024 ~~OPPS final rule issued in November 2023~~, Barostim was reassigned to New Technology APC 1580, which carries an average payment amount of $ 45, 000. The **APC payment of approximately $ 45, 000 will continue in 2025, as published in the 2025 OPPS final rule. In August 2024, CMS reassigned the Barostim implant procedure for the inpatient setting as part of the IPPS final rule for CMS' Fiscal Year 2025, which took effect on October 1, 2024. On that date, Barostim was reassigned to MS- DRG 276, which carries a national average payment of approximately $ 44, 000 in 2025, a significant increase from the previous payment range of $ 17, 000- $ 23, 000. Additionally, the American Medical Association' s CPT Editorial Panel approved** new ~~payment took~~ **Category I codes for Barostim therapy, expected to take** effect January 1, ~~2024~~ **2026**. Any future decline in the amount Medicare is willing to reimburse our customers for procedures using Barostim could make it difficult for new customers to adopt Barostim and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business **, or establish Barostim as the standard of care**. From time to time, physicians and hospitals have in the past experienced, and others may experience, ~~delays~~ **denials** in Medicare **and commercial** reimbursement, which have delayed or may delay their willingness to schedule additional Barostim procedures. A pandemic, epidemic or outbreak of an infectious disease in the U. S. or worldwide could adversely affect our business. Pandemics, epidemics **,** or outbreaks of an infectious disease may adversely affect our business. Numerous state and local jurisdictions have historically 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 infectious disease. Such orders or restrictions previously resulted, and may in the future result, in reduced operations at our headquarters, slowdowns and delays, travel restrictions and cancellation of events and restrictions on the ability of our front- line sales representatives to attend procedures in which our products are used, among other effects, thereby negatively impacting our operations. Other disruptions or potential disruptions include restrictions on the ability of our sales representatives and other personnel to travel and access customers for training and case support; the ability of hospitals and surgical centers to staff and conduct procedures; inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; delays in actions of regulatory bodies; and delays in clinical trials and studies, especially if study subjects are reluctant to present themselves at medical facilities. While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease may be difficult to assess or predict, it may result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. To the extent a pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this " Risk Factors " section. Risks related to intellectual propertyWe may in the future become involved in lawsuits to protect or enforce our intellectual property or defend ourselves against intellectual property disputes, which could be expensive, time consuming and ultimately unsuccessful, and could result in the diversion of significant resources, thereby hindering our ability to effectively commercialize our existing or future products. Our success depends in part on obtaining, maintaining **,** and enforcing patents and other intellectual property rights and 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~~ **52suffer**. Significant litigation regarding patent rights occurs in the medical device industry. Whether merited or not, it is possible that third parties controlling U. S. and foreign patents allege such patents cover our products, or we may decide to initiate infringement claims or litigation to protect our patents or other intellectual property rights. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Our competitors in both the U. S. and abroad, many of which ~~52have --~~ **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, or export our products. These competitors may have one or more patents for which they can threaten or initiate patent infringement actions against us or any of our third- party suppliers. Further, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages **,** or attorneys' fees. Moreover, if we initiate an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable or that the patent in question does not cover the technology at issue. From time to time and in the ordinary course of business, we may develop noninfringement or invalidity positions with respect to third- party patents, which may or may 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 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. 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 require 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 FDA regulatory clearance; • find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; or • redesign those products or processes that infringe any third- party intellectual property, which could be costly, disruptive , or infeasible. If a court determines that we failed to secure necessary patents, competitors may be able 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. 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~~ **53normal** responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and 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. ~~53Finally --~~ **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 our industry grows, the possibility of intellectual property infringement disputes 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 **United States Patent and Trademark Office (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. 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. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. 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 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. 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, may affect patent litigation and switched the U. S. 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 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, became effective on March 16, 2013. 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~~ **54In** 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. ~~54Furthermore --~~ **Furthermore** , the U. S. and foreign courts are continually interpreting various aspects of patent law. We cannot predict with any reasonable certainty how the evolution of the interpretation of these laws will affect our business. However, it is possible that changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of

procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business. 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 U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S. 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 lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed. 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- disclosure or confidentiality 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 about former employers or competitors. 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~~ **55in** the future be subject to claims that we caused an employee to breach the terms of his or her non- disclosure or confidentiality 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, resulting in litigation. Even if we are successful in defending against these claims, the litigation could be costly ~~55and~~ -- **and** a distraction to management. If we are unsuccessful in defending against these claims, 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. 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 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 and our 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 will be sufficient. 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 U. S. are reluctant 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 with whom they share it, from using that technology or information to compete with us and our competitive position could ~~be~~ **56be** adversely affected. If our intellectual property is not adequately protected to protect our market against competitors' products and methods, our competitive position and business could be adversely affected. ~~56Risks~~ -- **Risks** related to our financial and operating resultsWe may be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all. Our operations have consumed substantial amounts of cash since inception, and we anticipate our expenses will increase as we continue to build our commercial sales force in the U. S., investigate the potential use of Barostim for the treatment of other HF conditions, continue to grow our business and operate as a public company. We believe that our growth will depend, in part, on our ability to fund our commercialization and research and development efforts. We believe that our existing cash, cash equivalents, short- term investments and revenue will be sufficient to meet our capital requirements and fund our operations for at least the next three years. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. As a result, we may need to seek additional funds in the future. If we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. For the fiscal years ended December 31, **2024 and** 2023 ~~and 2022~~ , net cash used in operating activities was $ 39. **1 million and $ 39.** 0 ~~million and $ 42. 7~~ million, respectively. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including, among others: • the scope and timing of our continued investment in our U. S. commercial infrastructure and sales force; • the costs of commercialization activities, including product sales, marketing, manufacturing **,** and distribution and hiring additional members for our direct sales and marketing team in the U. S.; • the degree and rate of market acceptance of Barostim; • the research and development activities we intend to undertake in order to pursue product enhancements and expand HF indications; • the costs of filing, prosecuting, defending **,** and enforcing any patent claims and other intellectual property rights; • our need to implement additional infrastructure and internal systems; • our ability to hire additional personnel to support our operations; and • the emergence of competing technologies or other adverse market developments. To finance certain of 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 could contain covenants that will restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation **,** or asset sale transactions. For example, our Loan and Security Agreement (the " Loan Agreement ") with Innovatus Life Sciences Fund I, LP (" Innovatus ") restricts us from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. 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 may be adversely affected. 57Our operating results may vary significantly annually or from quarter to quarter, which may negatively impact our stock price in the future. Our revenue and results of operations may fluctuate annually or from quarter to quarter due to, among others, the following reasons: • physician and ~~payor~~ **payer** acceptance of Barostim and Barostim Therapy; • the timing, expense and results of research and development activities, clinical trials **,** and regulatory approvals; • fluctuations in our expenses associated with expanding our commercial operations and operating as a public company; • the introduction of new products and technologies by our competitors; • the productivity of our sales representatives; • supplier, manufacturing **,** or quality problems with our products; • the timing of stocking orders from our distributors; • changes in our pricing policies or in the pricing policies of our competitors or suppliers; and • changes in coverage amounts or government and third- party ~~payors~~ **payers** ' reimbursement policies. Because of these and other factors, it is possible that 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 also cause a fluctuation in our stock price. 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. Our product consists of a substantial number of individual components. In order to market and sell Barostim effectively, we often must maintain high levels of inventory. The manufacturing process requires lengthy lead times, during which components of our products may become obsolete, and we may over- or under- estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third- party manufacturers for our component parts exposes us to greater lead times. The seasonality of our business creates variance in our quarterly revenue, which makes it difficult to compare or forecast our financial results. We ~~expect that revenue could fluctuate from~~ **have seen seasonally lower rates of implants in our first fiscal** quarter ~~to quarter as a result of timing and seasonality. We anticipate mild seasonality based on national holiday patterns specific to certain nations. These seasonal variations are difficult to predict accurately, may vary amongst different markets, and at times may be entirely unpredictable. In addition to the above factors,~~ in ~~the~~ **recent years, which we believe is primarily due to** U. S. ~~it is possible that we may experience seasonality based on~~ patients ' **shifting medical treatments to the later months of the year when they have better information about spending against the** annual

deductibility limits under their health insurance coverage ~~. While historically seasonality has been minimal~~ , **and** we **expect this trend** ~~anticipate increased seasonality due~~ to **continue** ~~our increased focus on sales within the U~~ . ~~S. These~~ **Otherwise, mild** seasonal variations are difficult to predict accurately ~~,~~ **and** may vary among different markets ~~and at times may be entirely unpredictable, which introduces additional risk into our business as we rely upon forecasts of customer demand to build inventory in advance of anticipated sales~~ . **We** ~~In addition, we believe our limited history commercializing our products has, in part, made our seasonal patterns more difficult to discern and therefore predict. 58We~~ 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 current business is located outside the U. S. 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. As a result, changes in the exchange rates between such foreign currencies, particularly the Euro and the U. S. dollar, could materially impact our reported results of operations and distort period to period ~~comparisons~~ **58comparisons** . 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 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, and we may not be able to utilize a significant portion of our net operating loss and tax credit carryforwards prior to their expiration. We have generated and expect to continue to generate significant federal and state net operating loss (" NOLs ") and tax credit carryforwards. As of December 31, ~~2023~~ **2024** , we had federal and state NOL carryforwards of approximately $ ~~389~~ **429** . ~~9~~ **7** million and $ ~~7~~ **8** . ~~3~~ **1** million, respectively. The federal NOLs began expiring in 2021 and state NOLs began expiring in 2020. As of December 31, ~~2023~~ **2024** , we had federal and state tax credit carryforwards of approximately $ ~~9~~ **10** . ~~8~~ **2** million and $ ~~2~~ **1** . ~~0~~ **7** million, respectively. The federal and state tax credit carryforwards began expiring in 2021 and begin expiring in 2028, respectively. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the legislation enacted on December 22, 2017 commonly referred to as the " Tax Cuts and Jobs Act, " as modified by the Coronavirus Aid, Relief, and Economic Security Act, federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs incurred in taxable years beginning after December 31, 2020 is limited. In addition, under Sections 382 and 383 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 NOLs and specified other tax credit carryforwards, such as research and development tax credits, to offset future taxable income and taxes. We may have previously experienced, and may in the future experience, one or more " ownership changes " for purposes of the rules under Section 382 and 383 of the Code, including in connection with our **initial public offering (the "** IPO **")** . If so, or if we do not generate sufficient taxable income, we may not be able to utilize a material portion of our NOLs and tax credits, even if we achieve profitability. If we are limited in our ability to use our NOLs and tax credits in future years in which we have taxable income, 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 by effectively increasing our future tax obligations. We are subject to complex tax rules, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations **,** and financial condition. We are subject to income and / or non- income taxes in the U. S., Switzerland, Italy, Germany, France **,** and the Netherlands, as well as the tax laws and regulations related to such matters. Tax accounting and compliance often involves complex issues, and judgment and interpretation is required in determining our provision for income taxes and other tax liabilities as well as the application of tax laws and regulations. In that respect, many jurisdictions have detailed transfer pricing rules, which require that all transactions with related parties be priced using arm' s length pricing principles within the meaning of such rules. The application of such transfer pricing rules, as well as of withholding taxes, goods and services taxes, sales taxes and other taxes is not always clear, and we may be subject to tax audits relating to such rules or taxes. ~~59We~~ **We** believe that our tax positions are reasonable, and our tax provisions and reserves are adequate to cover any potential liability. However, various items cannot be accurately forecasted, and future events may be treated as discrete to the period in which they occur. In addition, the Internal Revenue Service or other taxing authorities may disagree with our positions. If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, we may be liable for additional tax and penalties and interest related ~~thereto~~ **59thereto** or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results, operations and future cash flow. Changes in U. S. and non- U. S. tax laws could adversely affect our financial condition and results of operations. The rules dealing with U. S. and non- U. S. tax matters are constantly under review by persons involved in the legislative, judicial, administrative, regulatory **,** and related governmental processes and authorities. Changes to tax laws or the interpretation and application thereof (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U. S. and non- U. S. tax laws could have a material adverse effect on our business, cash flow, financial condition **,** or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U. S. and non- U. S. tax laws on an investment in our common stock. Risks related to regulation of our industryBarostim is subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer. The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the EU legislative bodies and the EEA member state competent authorities. The FDA and other U. S., EEA and foreign governmental agencies and authorities regulate and oversee, among other things, with

respect to medical devices: • design, development and manufacturing; • testing, labeling, content , and language of instructions for use and storage; • clinical trials; • product safety; • marketing, sales , and distribution; • pre- market regulatory clearance and approval; • conformity assessment procedures; • record- keeping procedures; • advertising and promotion; • recalls and other field safety corrective actions; • post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; • post- market studies; and • product import and export. The laws and regulations to which we are subject are complex and have tended to become more stringent over time. Legislative or regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. ~~60Our~~ -- **Our** failure to comply with U. S. federal and state regulations or EEA or other foreign regulations applicable in the countries where we operate could lead to the issuance of warning letters or untitled letters, fines, injunctions, suspensions or loss of regulatory clearance or approvals, recalls or seizures of products, termination of distribution, or civil penalties. In the most extreme cases, criminal sanctions or closure of our ~~manufacturing~~ **60manufacturing** facilities are possible. If any of these risks materialize, our business would be adversely affected. Barostim is also subject to extensive governmental regulation in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer. In the EEA, Barostim was required to comply with the Essential Requirements laid down in Annex I to the EU Active Implantable Medical Devices Directive. Compliance with these requirements was a prerequisite to affixing the CE mark to Barostim. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark to Barostim, we underwent a conformity assessment procedure, which varied according to the type of medical device and its classification. Except for low- risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer could issue an EU Declaration of Conformity based on a self- assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure required the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body would audit the Quality Management System and examine the Technical File for the manufacture, design , and final inspection of our devices. The Notified Body would issue a CE Certificate of Conformity following successful completion of this conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate would entitle the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EU Declaration of Conformity. As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based on, among other things, the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e. g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. With respect to active implantable medical devices or Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming. In order to continue to sell Barostim in Europe, we must comply with the MDR and its evolving transition requirements. We have submitted our application for Barostim to comply with the general safety and performance requirements of the EU MDR (which are similar to the Essential Requirements of the AIMDD), and it is currently under review. Additionally, the EU ~~did approve~~ **approved** an amendment to the MDR ~~which~~ **that** allows qualifying AIMDD CE certificates to be accepted through December of 2027. We have already met the qualifications identified within this amendment to allow continued distribution of Barostim through this time. Failing to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body (the National Standards Authority of Ireland, or NSAI), which could impair our ability to market products in the EEA in the future. ~~61Our~~ -- **Our** business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to market Barostim in the U. S. and introduce new or improved products. Our products must comply with regulatory requirements imposed by the FDA in the U. S. and similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing ~~procedures~~ **61procedures** , sampling activities, extensive agency review processes and other costly and time-consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. Some of the most important requirements we must comply with include: • the FDCA and the FDA' s implementing regulations (Title 21 CFR); • EU CE mark requirements; • Medical Device Quality Management System Requirements (ISO 13485: 2003); • Occupational Safety and Health Administration requirements; and • California Department of Health Services requirements. Current or evolving government regulation may impede our ability to conduct clinical studies and to manufacture and sell our existing and future products. Such government regulation also could delay our marketing of new products for a considerable period of time and impose costly procedures on our activities. **The extended times EU notified bodies are taking to review and approve both the original MDR application and significant changes once approved, may limit or cause delays in our ability to make necessary or desired changes to the design, manufacturing processes, materials, or quality**

management system. 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 research and development programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations. 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 inappropriate promotion. Barostim has been indicated for the improvement of symptoms of HFrEF by the FDA and the treatment of HFrEF in the EEA. We may only promote or market Barostim for its specifically approved indications as described on the approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as " off- label uses. " We cannot, however, prevent a physician from using our product off- label when, in the physician' s independent professional medical judgment, he or she deems appropriate. There may be increased risk of injury to patients if physicians attempt to use our product off- label. Furthermore, the use of our product for indications other than those approved by the applicable regulatory 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, 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 product liability claims or other litigation by our customers or their patients. In addition, if the FDA determines that our promotional materials or training constitute promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if ~~62they --~~ **they** consider our business activities to constitute inappropriate promotion, including promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and / or administrative ~~penalties~~ **62penalties** , damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. Any of these events could significantly harm our business and results of operations and cause our stock price to decline. Further, the advertising and promotion of our products is subject to EEA member state laws implementing the MDD, Directive 2006 / 114 / EC concerning misleading and comparative advertising and Directive 2005 / 29 / EC on unfair commercial practices, as well as other EEA member state legislation governing the advertising and promotion of medical devices. EEA member state legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. The discovery of serious safety issues with Barostim, or a recall of Barostim either voluntarily or at the direction of the FDA or another governmental authority, could harm our reputation, business **,** and financial results. The FDA, the competent authorities of the EEA 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 or in the event that a product poses an unacceptable risk to health. 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. We may also choose to 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 an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects, packaging defects or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Recalls, which include certain notifications and corrections as well as removals, of Barostim could divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation 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 FDA' s 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 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 or approvals, product seizures, injunctions **,** or the imposition of civil or criminal penalties, which would adversely affect our business results and prospects. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals for the device before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement actions, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall ~~63announcement --~~ **announcement** could harm our reputation with

customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ~~ourselves~~ **63ourselves** in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA and European regulators, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition **,** and results of operations. 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 EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the MDD, an incident is defined as any malfunction or deterioration in the characteristics and / or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or European regulators could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device approval, seizure of our products or delay in clearance or approval of future products. We are subject to certain federal, state **,** and foreign fraud and abuse laws, transparency and privacy and security laws and regulations, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws and regulations could cause adverse publicity and be costly to respond to, and thus could harm our business. There are numerous U. S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti- kickback, false claims **,** and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We are subject to privacy and security regulation related to patient, customer, employee **,** and other third- party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the U. S., the laws that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it; • federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment 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; ~~64~~ • the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence ~~the~~ **64the** beneficiary' s decision to order or receive items or services reimbursable by the government from a particular provider or supplier; • the federal HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the Anti- Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them; • HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements; • the federal physician payments sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics **,** and medical supplies to report annually to HHS information related to payments and other transfers of value to certain healthcare providers and teaching hospitals; • state and foreign law analogs 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~~ **payer** , including commercial insurers; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of personal and health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA. These laws and regulations, among other things, constrain our business, marketing **,** and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians **,** or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to increase

their scrutiny of interactions between healthcare companies and healthcare providers. The Office of the Inspector General of HHS also has issued compliance program guidance for pharmaceutical manufacturers which is routinely applied to medical device companies. All of this has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry, including for medical device companies. 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. 65Healthcare legislative reform measures may have a material adverse effect on us. In the U. S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the U. S., which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act: • established a new Patient- Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; • implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians **,** and other providers to improve the coordination, quality **,** and efficiency of certain healthcare services through bundled payment models; and • expanded the eligibility criteria for Medicaid programs. The expansion in the government' s role in the U. S. healthcare industry may result in decreased profits to us, lower reimbursement by ~~payors~~ **payers** for Barostim and any future products and / or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition **,** and results of operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services. Additionally, on April 5, 2017, the European Parliament passed the MDR, which repeals and replaces the MDD and the AIMDD. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations are directly applicable (i. e., without the need for adoption of the EEA member state laws implementing them), in all EEA member states and are intended to eliminate differences in the regulation of medical devices among the EEA member states. The MDR, among other things, is intended to establish a uniform, transparent, predictable **,** and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The MDR **is set to** ~~became~~ **become** effective in ~~May~~ **January** ~~2021~~ **2028** and, among other things is designed to: • strengthen the rules on placing devices on the market and reinforce surveillance once they are available; • establish explicit provisions on manufacturers' responsibilities for the follow- up of the quality, performance and safety of devices placed on the market; • improve the traceability of medical devices throughout the supply chain to the end- user or patient through a unique identification number; • set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and • strengthen rules for the assessment of certain high- risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market. This regulation has not yet had a material effect on the way we conduct our business in the EEA. However, it is possible the regulation will change in the future, and we cannot be certain that future changes will not have an adverse effect on our business operations. 66Risks related to our common stock We expect that the price of our common stock will fluctuate substantially, and you may not be able to resell shares of our common stock at or above the price you paid. The market price of our common stock has been and may continue to be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including: • results from, or any delays in, clinical trial programs relating to our product candidates, including the ongoing and future U. S. clinical trials for Barostim; • announcements of new products by us or our competitors; • adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities; • our operating results; • changes or developments in laws or regulations applicable to our products; • any adverse changes in our relationship with any manufacturers or suppliers; • the success of our efforts to acquire or develop additional products; • any intellectual property infringement actions in which we may become involved; • announcements concerning our competitors or the medical device industry in general; • achievement of expected product sales and profitability; • ~~manufacture~~ **manufacturing** , supply or distribution shortages; • actual or anticipated fluctuations in our operating results; • FDA or other U. S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the U. S.; • changes in financial estimates or recommendations by securities analysts; • trading volume of our common stock; • sales of our common stock by us, our executive officers and directors or our stockholders in the future; • general economic and market conditions and overall fluctuations in the U. S. equity markets; and • the loss of any of our key scientific or management personnel. In addition, the stock markets in general, and the markets for 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. In the past, when the market price of a stock has been volatile or decreases significantly, 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 results of operations and financial position. Any adverse determination in litigation could also subject us to significant liabilities. 67Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price and trading volume to 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 no or few securities or industry analysts cover us, the trading price for our stock would be negatively impacted. 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. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. We are an " emerging growth company, " and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $ 1. 235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non- affiliates exceeds $ 700 million as of the prior June 30th, and (2) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. Because we have opted to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, our financial statements may not be directly comparable to other public companies. Pursuant to the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. Because we have elected to take advantage of this provision of the JOBS Act, our financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies. 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 could be adversely affected. To comply with the requirements of being a public company, we are undertaking and expect to continue to undertake various actions, including implementing and maintaining new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes- Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We have developed and expect to continue to refine our disclosure controls and other procedures that are designed to ensure that 68information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. 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. The Sarbanes- Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an " emerging growth company, " as defined by the JOBS Act, and are not a non- accelerated filer. We do not expect to have our independent registered public accounting firm attest to our management report on internal control over financial reporting for so long as we are an emerging growth company. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. If we fail to develop and maintain effective internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have designed and implemented and expect to continue to refine the internal control over financial reporting required to comply with this obligation, which process will be 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 of the Sarbanes- Oxley Act in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or, when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, or if our internal control over financial reporting is perceived as inadequate or we are unable to produce timely or accurate financial statements, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline and we could become subject to investigations or removal by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources. Our principal stockholders, management **,** and directors (~~two~~ **one** of whom ~~are~~ **is** affiliated with **one of** our principal stockholders) own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of December 31, ~~2023~~ **2024** , our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately ~~52~~ **43** % of our outstanding voting stock. ~~Two~~ **One** of our non- employee directors ~~are~~ **is** also affiliated with ~~certain~~ **one** of our principal stockholders. Therefore, if they act together, these stockholders will have the ability to influence us through this ownership position and matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction.

The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the Company, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers , or employees. Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law (the " DGCL ") or any action asserting a claim 69against us that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation also provides that the U. S. federal district courts are the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees , or agents and arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. Under the Securities Act, federal and state courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, these provisions may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder' s ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition , and results of operations. Anti- takeover provisions included in our amended and restated certificate of incorporation and amended and restated bylaws, as well as under Delaware law, could discourage a takeover. Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that may discourage, delay , or prevent a merger, acquisition , or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace or remove current members of our management team. These include the following provisions that: • permit our Board of Directors to issue shares of preferred stock, with any rights, preferences , and privileges as they may designate, without stockholder approval, which could be used to dilute the ownership of a hostile bidder significantly; • provide that the authorized number of directors may be changed only by resolution of our Board of Directors and that a director may only be removed with cause by the affirmative vote of the holders of at least a majority of our outstanding voting stock, voting together as a single class; • provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; • provide that our amended and restated bylaws may only be altered, amended , or repealed by our stockholders upon the affirmative vote of a two- thirds majority of the voting power of all of our outstanding voting stock, voting together as a single class; • provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder' s notice, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the 70