Risk Factors Comparison 2024-02-29 to 2023-03-01 Form: 10-K

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Investing in our securities involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report on Form 10- K, including our consolidated financial statements, the notes thereto and the section entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The occurrence of any of these risks could have a material and adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. Certain statements contained in this section constitute forward- looking statements. See the information included in " Special Note Regarding Forward- Looking Statements " in this Annual Report on Form 10- K. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. **Risk Factors Summary The following is a summary of some of the risks and uncertainties as of the date of the filing of this Annual Report on Form 10- K that could materially adversely affect our business, financial condition, and / or results of operations. You should read this summary together with the more detailed description of each risk factor contained below.** Risks Related to Our **Proposed Merger with Boston Scientific • Failure to complete, and delays in completing, the Merger with Boston Scientific could materially and adversely affect our results of operations and our stock price. • The ability to complete the Merger is subject to the receipt of consents and approvals from government entities, which may impose conditions that could have an adverse effect on us or the combined company or could cause either party to abandon the Merger. • We are subject to various uncertainties and restrictions on the conduct of our business while the Merger is pending. • We will continue to incur substantial transaction- related costs in connection with the Merger. • We and our directors and officers may be subject to lawsuits relating to the Merger. • Provisions of the Merger Agreement may deter alternative business combinations and could negatively impact our stock price if the Merger Agreement is terminated in certain circumstances. Risks Related to Our** Business and Strategy • We have incurred significant operating losses since inception, and we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability **. • We are substantially dependent on the success of our SNM systems. • We rely on third parties for the manufacture of our products, which could delay, prevent or impair our development or commercialization efforts. • We depend on single source suppliers to manufacture certain of our components, sub- assemblies and materials for our SNM systems, which makes us vulnerable to supply shortages and price fluctuations. • Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory. • We have a limited history of manufacturing and assembling our products in commercial quantities. • Any additional capital required to finance our planned operations may not be available to us on acceptable terms or at all. • We compete against other companies, which may prevent us from achieving increased market penetration and improved operating results. • Any termination or loss of significant rights under the License Agreement would materially and adversely affect our development and commercialization of our rechargeable SNM system. • If we are not successful in converting physicians and patients to our products, our business will not succeed. • Our long- term growth substantially depends, in part, on our ability to enhance our products. • If the quality and benefits of our products do not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected. • If our estimates and projections overestimate the size and future growth in the market for SNM therapy and urethral bulking agent, our sales growth may be adversely affected. • Our potential collaborations, in- licensing arrangements, joint ventures, strategic alliances or partnerships may not result in commercially viable products, product improvements or significant future revenues. • The failure to manage future acquisitions, or to integrate them with our existing business, could harm our business, financial condition and operating results. • Potential complications from our products or future enhancements to our products may not be revealed by our clinical experience. • If we fail to receive access to hospital facilities, our sales may decrease. • Performance issues, service interruptions or price increases by shipping carriers could adversely affect our business and harm our reputation and ability to provide our products on a timely basis. • Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions. • To successfully market and sell our products in markets outside of the United States, we must address many international business risks with which we have limited experience. • Our ability to maintain our competitive position depends on our ability to attract and retain senior management and other highly qualified personnel. • If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our products, our commercial success may be severely hindered. • We face the risk of product liability claims that could be expensive, divert management' s attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance. • Failure of a key information technology system, process, or site could have an adverse effect on our business. • If our facilities are damaged or become inoperable, we will be unable to continue to research and develop our products. • Failure to comply with anti- bribery, anti- corruption, and anti- money laundering laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations could subject us to civil or criminal penalties, other remedial measures and legal expenses. • Unfavorable global economic conditions could adversely affect our business, financial condition, or results. • A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the COVID- 19 virus, could adversely affect our business. • Security breaches, cyber- attacks, loss of data or other disruptions or incidents could expose us to liability and affect our business and reputation. Risks Related to Legal**

Matters and Government Regulation • Our operations are subject to extensive laws and government regulation and oversight both in the United States and internationally, and our actual or alleged failure to comply with applicable requirements could harm our business. • We may not receive the necessary clearances or approvals for modifications to our products, and failure to do so would adversely affect our ability to grow our business. • The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies. • If clinical studies of our products do not produce results necessary to support regulatory clearance or approval, we will be unable to expand the indications for our products and may incur additional costs or experience delays in the commercialization of our products. • Failure to comply with post- market regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw our products from the market. • We or any of our suppliers or manufacturers could be forced to recall our products or terminate production. • If treatment guidelines for OAB, SUI, FI or UR change or the standard of care evolves, we may need to redesign and seek a new marketing authorization from the FDA for our products. • Our products may cause or contribute to adverse medical events or serious safety issues. • Legislative or regulatory reforms in the United States or Europe may make it more difficult and costly for us to obtain regulatory clearances or approvals, or to manufacture, market or distribute our products. Risks Related to Intellectual Property • Litigation or other proceedings or third- party claims of intellectual property infringement against us, including the Medtronic Litigation, or any of our current or future licensors, including Alfred E. Mann Foundation for Scientific Research (AMF), could require us to spend significant time and money and could prevent us from selling our products, or affect our stock price. • If we or any of our current or future licensors, including AMF, are unable to maintain, obtain or adequately protect our intellectual property rights, we may not be able to compete effectively in our market or we could be required to incur significant expenses to enforce or defend our rights or attempt to do the same. • If we are unable to enforce our intellectual property or protect the confidentiality of our trade secrets or our confidential information, our business or competitive position could be harmed. • Third parties may assert ownership or commercial rights to inventions we develop. • If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business. Risks Related to Our Common Stock • We are obligated to maintain proper and effective internal controls over financial reporting and any failure to do so may adversely affect investor confidence in us, and, as a result, the value of our common stock. • Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. • If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. On January 8, 2024, we entered into the Merger Agreement with Boston Scientific pursuant to which, upon the terms and subject to the conditions of the Merger Agreement, if all of the conditions to closing are satisfied or waived, Merger Sub, a wholly owned subsidiary of Boston Scientific, will merge with and into Axonics, with the separate corporate existence of Merger Sub thereupon ceasing and Axonics continuing as the surviving company and a wholly owned subsidiary of Boston Scientific. The consummation of the Merger is subject to a number of customary closing conditions, including stockholder approval and the expiration or termination of the waiting period (and any extensions) applicable to the Merger under the HSR Act, among others, a number of which are not within our control. Failure to satisfy the conditions to the Merger could prevent, delay or otherwise materially and adversely affect the completion of the Merger. We can provide no assurance that all required approvals and clearances will be obtained or that all closing conditions will be satisfied, and, if all required approvals and clearances are obtained and the closing conditions are satisfied, we can provide no assurance as to the terms, conditions and timing of such approvals or the timing of the completion of the Merger. We also cannot assure you that we will be able to successfully consummate the Merger as currently contemplated under the Merger Agreement or at all. Risks related to the failure of the Merger to be consummated include, but are not limited to, the following: • the Merger may be subject to certain legal restraints or challenge under applicable antitrust law outside the United States and may also be subject to scrutiny under U. S. antitrust law, even following the expiration of the waiting period (and any extensions) under the HSR Act; • we would not realize any or all of the potential benefits of the Merger, including any synergies that could result from combining our financial and proprietary resources with those of Boston Scientific, which could have a negative effect on the price of our common stock; • under some circumstances, we may be required to pay a termination fee to Boston Scientific of $ 75 million; • we will remain liable for significant transaction costs, including legal, accounting, financial advisory, and other costs relating to the Merger regardless of whether the Merger is consummated; • we may experience negative reactions from financial markets or the trading price of our common stock may decline to the extent that the current market price for our common stock reflects a market assumption that the Merger will be completed; • the attention of our management and employees may have been diverted by the Merger; • we and our directors and officers could be subject to litigation relating to the Merger, including relating to any failure to complete the Merger; • the potential loss of key personnel during the pendency of the Merger as employees may experience uncertainty about their future roles with us following completion of the Merger; • the potential loss of, and negative reactions from physicians, patients, payors, suppliers, hospitals, manufacturers, and other business partners, including those with which we are seeking to establish business relationships, due to uncertainties about the Merger, and; • under the Merger Agreement, we are subject to certain restrictions on the conduct of our business prior to completing the Merger, which restrictions could adversely affect our ability to conduct our business as we otherwise would have done if we were not subject to these restrictions. The occurrence of any of these events individually or in combination could materially and adversely affect our business, results of operations, financial condition, and stock price. If the Merger is not consummated and one or more of these events occur, such as payment of a termination fee to Boston Scientific or other significant transaction costs in

connection with the Merger, our cash balances and other outstanding indebtedness at that time could be materially and adversely impacted and our options for sources of financing or refinancing could be more limited than if we had not pursued the Merger. If the Merger is not completed, there can be no assurance that these risks will not materialize and will not materially and adversely affect our stock price, business, financial condition, results of operations or cash flows. Completion of the Merger is conditioned upon, among other things, the expiration or termination of the required waiting period (and any extension thereof) applicable to the Merger under the HSR Act, and the rules and regulations promulgated thereunder, and required consents, approvals, non- disapprovals and other authorizations under certain foreign antitrust or competition laws or foreign investment laws. We cannot provide any assurance that we or Boston Scientific will obtain the necessary consents, approvals, non- disapprovals and other authorizations or that the U. S. or foreign antitrust or foreign investment authorities will not take action under applicable antitrust and foreign investment laws in respect of the pending Merger. At any time before or after consummation of the Merger, the FTC or DOJ could take such action under the antitrust laws as it deems necessary or desirable in the public interest, including seeking to enjoin the completion of the Merger, seeking divestiture of substantial assets of one or both of the parties, requiring the parties to license or hold separate assets or terminate existing relationships and contractual rights, or requiring the parties to agree to other remedies. At any time before or after the completion of the Merger, and notwithstanding expiration of the waiting period under the HSR Act, any state or foreign jurisdiction could take such action under the antitrust laws as it deems necessary or desirable in the public interest. Such action could include seeking to enjoin the completion of the Merger, seeking divestiture of substantial assets of one or both of the parties, requiring the parties to license or hold separate assets or terminate existing relationships and contractual rights, or requiring the parties to agree to other remedies. Under certain circumstances, we or Boston Scientific may be permitted to terminate the Merger Agreement in the event that the required waiting period (and any extension thereof) applicable to the Merger under the HSR Act has not expired or been terminated or required consents, approvals, non- disapprovals and other authorizations under certain foreign antitrust or competition laws or foreign investment laws have not been obtained by the one- year anniversary of the date of the Merger Agreement (subject to extension as permitted under the Merger Agreement). Private parties may also seek to take legal action under the antitrust laws under certain circumstances, including by seeking to intervene in the regulatory process or litigate to enjoin or overturn regulatory approvals, any of which actions could significantly impede or even preclude obtaining required regulatory approvals. We cannot be certain that a challenge to the Merger will not be made or that, if a challenge is made, we will prevail. We are subject to various uncertainties and restrictions on the conduct of our business while the Merger is pending, which could have a material adverse effect on our business, results of operations and financial condition. Uncertainty about the pendency of the Merger and the effect of the Merger on our employees, customers, suppliers, manufacturers, and other third parties who deal with us may have a material adverse effect on our business, results of operations and financial condition. These uncertainties may impair our ability to attract, retain and motivate key personnel pending the consummation of the Merger, as such personnel may experience uncertainty about their future roles following the consummation of the Merger. Additionally, these uncertainties could cause physicians, patients, payors, suppliers, hospitals, manufacturers, and other business partners who deal with us to seek to change existing business relationships with us or fail to extend an existing relationship with us, including, but not limited to, the pendency of purchasing contracts and bidding processes that would enable physicians to use our products, all of which could have a material adverse effect on our business, results of operations, financial condition and market price of our common stock. In addition, the Merger Agreement restricts us from taking certain actions without Boston Scientific' s consent while the Merger is pending. These restrictions may, among other matters, prevent us from hiring key personnel, buying or selling assets, making certain capital expenditures, refinancing or incurring additional indebtedness, entering into transactions, or making other changes to our business prior to consummation of the Merger or termination of the Merger Agreement. These restrictions and uncertainties could have a material adverse effect on our business, results of operations and financial condition during the pendency of the Merger. We have incurred significant legal, advisory and financial services fees in connection with Merger. We have incurred, and expect to continue to incur, additional costs in connection with the satisfaction of the various conditions to closing of the Merger, including seeking approval from our stockholders and from applicable regulatory authorities. If there is any delay in the consummation of the Merger, these costs could increase significantly. Litigation is very common in connection with the sale of public companies, regardless of whether the claims have any merit. One of the conditions to consummating the Merger is that no order enjoining, prohibiting or otherwise making illegal the consummation of the Merger shall have been issued by any governmental authority, including a court. Consequently, if any lawsuit challenging the Merger is successful in obtaining an order preventing the consummation of the Merger, that order may delay or prevent the Merger from being completed. While we will evaluate and defend against any lawsuits, the time and costs of defending against litigation relating to the Merger may adversely affect our business. The Merger Agreement prohibits us from soliciting, initiating, knowingly facilitating or knowingly encouraging any inquiries, proposals or offers that would be reasonably expected to lead to certain alternative takeover proposals with any third party, and from taking other similar actions, subject to exceptions set forth in the Merger Agreement. The Merger Agreement also provides for the payment by us of a termination fee of $ 75 million if the Merger Agreement is terminated in certain circumstances in connection with a competing third- party acquisition proposal. These provisions limit our ability to pursue offers from third parties that could result in greater value to our stockholders. The obligation to pay the termination fee may also discourage a third party from pursuing an alternative acquisition proposal. If the Merger Agreement is terminated and we determine to seek another business combination, we cannot assure our stockholders or other securities holders that we will be able to negotiate a transaction with another

company on terms comparable to the terms of the Merger Agreement, or that we will avoid incurrence of any fees associated with the termination of the Merger Agreement. In the event the Merger Agreement is terminated, our stock price may decline . We are a medical technology company with a limited commercial operating history. To date, we have invested substantially all of our efforts in the research and development of, seeking regulatory approval for, and commercialization of our SNM systems. We are not profitable and have incurred losses each year since we began our operations in 2013. We have a limited commercial operating history upon which to evaluate our business and prospects. We expect that our operating expenses will continue....., and results of operations. We have not yet derived sufficient revenues to support our operations, as our activities prior to 2022 have consisted primarily of investing in our commercial operations, developing our technology, conducting clinical studies, and developing our sales force. As a result, we have recorded net losses of $ **6. 1 million, $** 59. 7 million, **and** $ 80. 1 ~~million, and $ 54. 9~~ million for the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~374~~ **380** . ~~3~~ **4** million. To date, we have financed our operations primarily through equity financings. We expect that our operating expenses will continue to increase as we (i) continue to expand our commercial infrastructure, (ii) develop, enhance, and expand the commercialization of our SNM systems in the United States, (iii) potentially seek additional FDA regulatory approvals for other future product candidates in the United States, and (iv) increase our commercialization efforts internationally. As a result, we expect to continue to incur operating losses for the foreseeable future ~~. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock~~ and **may never achieve profitability** ~~our ability to raise capital and continue operations~~ . ~~If~~ **Furthermore, even if** we do **achieve profitability** ~~not generate sufficient revenue~~ , we may not be able to ~~achieve profitability. Even if we do achieve profitability, we may not be able to~~ sustain or increase profitability ~~in subsequent periods or~~ on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material ~~and~~ adverse effect on our business, financial condition and results of operations ~~expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure,invest in research and development~~ ,and ~~develop~~ **cause the market price of our common stock to decline.Our expected future operating losses** , ~~enhance~~ **combined with our prior operating losses** , **may adversely affect the market price of our common stock** and ~~commercialize new products~~ **our ability to raise capital and continue operations** .As a result,we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability.Furthermore,even if we do achieve profitability,we may not be able to sustain or increase profitability on an ongoing basis.If we do not achieve or sustain profitability,it will be more difficult for us to finance our business and accomplish our strategic objectives,either of which would have a material adverse effect on our business,financial condition ~~,~~ **and** results of operations, ~~and cause the market price of our common stock to decline.~~ and cause the market price of our common stock to decline. Our SNM systems currently represent the majority of our sales, and we are substantially dependent on the success of our SNM systems. Until we acquired the Bulkamid product on February 25, 2021 **and received FDA approval of our recharge- free SNM system in March 2022** , our rechargeable SNM system was our sole product. We expect our SNM ~~systems~~ **system** to drive the majority of our sales for the foreseeable future. As a result, we are substantially dependent on its success. We expect that it will take time for us to increase adoption of our Bulkamid products. Successfully commercializing medical devices such as ours is a complex and uncertain process. Our commercialization efforts depend on the efforts of our management and sales team, our third- party manufacturers and suppliers, physicians and hospitals, and general economic conditions, among other factors, including the following: • the effectiveness of our marketing and sales efforts in the United States and internationally; • our success in educating physicians and patients about the benefits, administration and use of our products; • the acceptance by physicians and patients of the safety and effectiveness of our products; • our third- party manufacturers' and suppliers' ability to manufacture and supply the components of our SNM systems in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements, and to remain in good standing with regulatory agencies; • the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing therapies; • our ability to obtain, maintain, and enforce our intellectual property rights in and to our **products** ~~SNM systems~~ ; • the emergence of competing technologies and other adverse market developments, and our need to enhance our products and / or develop new products to maintain market share in response to such competing technologies or market developments; • our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products; and • our ability to achieve and maintain compliance with all regulatory requirements applicable to our products. We hired and trained sales representatives and clinical specialists with strong backgrounds and experience in SNM therapy and other neurostimulation applications, and who have existing relationships with urologists and urogynecologists. However, we expect that our sales force will **continue to** require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products will often require or benefit from direct support from us. 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. Also, to the extent any of our sales force is comprised of personnel hired from our competitor, we may have to wait until applicable non- competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. This may subject us to allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Addressing such allegations would be costly both in terms of time and resources. Any of these risks may adversely affect our business. We rely on third parties for the manufacture of our products. This reliance on third parties increases the risk that we will not have sufficient quantities of our products or such quantities at an acceptable cost, and reduces our control over the manufacturing process, which could delay, prevent or impair our development or commercialization efforts. We currently rely, and expect to continue to rely, on third- party manufacturers for the manufacture of certain components of our products. For our off- the- shelf

components, we do not have long- term supply agreements with many of our third- party manufacturers, and we purchase certain components for our products on a purchase order basis. We may be unable to establish any agreements with third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • the possible failure of the third party to manufacture any such component of our products according to our schedule, or at all, including if our third- party ~~contractors~~ **manufacturers** give greater priority to the supply of other products over ours or otherwise do not satisfactorily perform according to the terms of the agreements and / or purchase orders between us and them; • the possible termination or nonrenewal of agreements by our third- party ~~contractors~~ **manufacturers** at a time that is costly or inconvenient for us; • ~~supplier~~ **manufacturer** demands for significant cost increases; • interruption of supply resulting from modifications to, or discontinuation of, a ~~supplier~~ **manufacturer** ' s operations; • the possible breach by the third- party manufacturers of our agreements with them; • the failure of third- party manufacturers to comply with applicable regulatory requirements; • price fluctuations due to a lack of long- term supply arrangements with our ~~suppliers~~ **manufacturers** for key components; • difficulty identifying and qualifying alternative ~~suppliers~~ **manufacturers** for components in a timely manner; • the possible failure of the third- party to manufacture any such components of our products according to our specifications; and • the possible misappropriation **or unauthorized disclosure** of our proprietary information, including our trade secrets and know- how. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with current Good Manufacturing Practice (cGMP) regulations applicable to our products. Third- party manufacturers may not be able, or fail, to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and / or maintain marketing approval for their manufacturing facilities. In addition, we do not have complete control over the ability of our third- party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Although we require our third- party ~~suppliers~~ **manufacturers** to supply us with components that meet our specifications and comply with applicable provisions of the FDA' s QSR and other applicable legal and regulatory requirements in our agreements ~~and contracts~~, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our ~~suppliers~~ **manufacturers** will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner. If the FDA or a comparable foreign regulatory authority withdraws any such approval they have already procured, we may need to find alternative manufacturing facilities, which would significantly impact our ability to market our products. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our products may adversely affect our future profit margins and our ability to commercialize our products on a timely and competitive basis. We depend on single source suppliers to manufacture certain of our components, sub- assemblies and materials for our SNM systems **and to manufacture Bulkamid** , which makes us vulnerable to supply shortages ~~and~~ **,** price fluctuations **and production and other problems with such suppliers** that could have a material adverse effect on our business, financial condition and results of operations. We rely on single source suppliers in many instances for certain of the components, sub- assemblies and materials for our SNM systems. These components, sub- assemblies and materials are critical and there are relatively few alternative sources of supply. We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub- assemblies and materials, and in some instances we do not carry a significant inventory of these items. While we believe that alternative sources of supply may be available, they may not be available if and when we need them, or alternative suppliers may not be able to provide the quantity and quality of components and materials that we would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses. ~~Our affect us.~~ We **also** depend solely upon Contura International for the manufacturing of Bulkamid,pursuant to the Manufacturing and Supply Agreement.Although alternative suppliers may exist,we are required to purchase Bulkamid exclusively from Contura International under the Manufacturing and Supply Agreement.Additionally,finding a replacement supplier with the capabilities required to manufacture Bulkamid could take a significant amount of our management' s time and resources,and no such additional supplier may exist.Further,obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non- infringement of third- party intellectual property **rights could** ~~results~~ **result in a significant interruption** of ~~operations~~ **supply and could require the new manufacturer to bear significant additional costs which may be passed on to us. In addition, our reliance on these single source suppliers entails additional risks, including reliance on their regulatory compliance and quality assurance and the continued compliance of their agreements with us. Any termination of their agreements with us to supply these components, sub- assemblies and materials for our SNM systems and, in the case of Contura International, to manufacture Bulkamid** could be ~~materially harmed if we~~ **costly or inconvenient to us. Our failure or the failure of our suppliers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our SNM systems or Bulkamid. Our dependence on these single source suppliers also subjects us to all of the risks related to such suppliers' respective businesses, which** are **all generally beyond** ~~unable to accurately forecast customer demand for~~ our ~~products~~ **control. These suppliers' ability to perform their respective obligations under their agreements with us is dependent on their**

operational and ~~manage our inventory~~ **financial health, which could be negatively impacted by several factors, including changes in the economic and political and legislative conditions** . To ensure adequate inventory supply, we must forecast inventory needs and place orders with suppliers based on our estimates of future demand for our products. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to adequately manage our expansion efforts, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast customer acceptance of new product enhancements, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write- downs or write- offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Similarly, a portion of our inventory could become obsolete or expire, which could have a material and adverse effect on our earnings and cash flows due to the resulting costs associated with inventory impairment charges and costs required to replace obsolete inventory. Any of these occurrences could negatively impact our financial performance. Conversely, if we underestimate customer demand for our products, we may not be able to deliver sufficient products to meet our customers' requirements, which could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or our third- party manufacturers may not be able to allocate sufficient resources to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our products and our results of operations. We have a limited history of manufacturing and assembling our products in commercial quantities and may encounter related problems or delays that could result in lost revenue. The manufacturing process of our products includes sourcing components from various third- party suppliers, assembly and testing. We must manufacture and assemble these systems in compliance with regulatory requirements and at an acceptable cost in order to achieve and maintain profitability. We have only a limited history of manufacturing and assembling our products and, as a result, we may have difficulty manufacturing and assembling our products in sufficient quantities in a timely manner. Our limited manufacturing history may not provide us with enough data to accurately predict future component demand, fluctuations in availability and pricing of commodity materials of supply, and, to anticipate our costs and supply needs effectively. We may, in the future, experience delays in obtaining components from suppliers, which could impede our ability to manufacture and assemble our products on our expected timeline. As a result of this or any other delays, we may encounter difficulties in production of our products, including problems with quality control and assurance, component supply shortages or surpluses (including with respect to the ceramic and titanium we use in our products), increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements. We will need to increase the size of our organization and we may be unable to manage our growth effectively. We have been growing rapidly in recent periods and have a relatively short history of operating as a commercial company. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth we will need to continue to improve our operational, compliance and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer. We may require additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development activities, conducting clinical studies for our products, and building our dedicated direct sales organization. Our expenses have also increased substantially in connection with the commercialization of our products in the United States, including hiring qualified personnel and retaining our sales team. We expect that certain of these activities and the associated expenses will continue. Additional expenditures also include costs associated with manufacturing and supply, sales and marketing costs, costs and expenses incidental to being a public company, and general operations. In addition, other unanticipated costs may arise. Our present and future funding requirements will depend on many factors, including: • the costs associated with manufacturing, selling, and marketing our products, including the cost and timing of implementing our sales and marketing plan and expanding our manufacturing capabilities; • our ability to retain and compensate the highly qualified personnel necessary to execute our plans; • our ability to effectively market and sell, and achieve sufficient market acceptance and market share for, our products; • the costs to maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights, including the Medtronic Litigation discussed under " Risks Related to Intellectual Property "; • our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements; • the timing, receipt, and amount of license fees and sales of, or royalties on, or future improvements on our products, if any; and • our need to implement additional internal systems and infrastructure, including financial and reporting systems, incidental to being a public company. We may need to raise additional capital, and if we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our SNM systems, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we are unable to obtain adequate financing when needed

and on terms that are acceptable to us, we may have to delay, reduce the scope of or suspend the implementation of our sales and marketing plan and our ongoing research and development efforts, which would have a material adverse effect on our business, financial condition, and results of operations. We compete against other companies offering first-, second- and third-line therapies for the treatment of OAB and SUI, including Medtronic and Boston Scientific, respectively, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration and improved operating results. We believe our SNM systems and our Bulkamid product are designed to offer several needed improvements in the SNM and bulking agent markets for patients, physicians, and payors. However, the medical technology industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants. We consider our primary competition to be other implantable SNM devices. On SNM, we face competition from major medical device companies worldwide, including Medtronic, the maker of InterStim X and InterStim Micro. InterStim X and InterStim Micro are currently the only other implantable SNM devices approved for commercial sale in the United States by the FDA. Competition from Medtronic could significantly impact our ability to capture and penetrate market share in the third- line therapy treatment market, and therefore could potentially have a material adverse effect on our business, financial condition and results of operation. We also compete with other less invasive third- line treatments for OAB and FI, such as BOTOX injections, a product sold by Allergan plc, PTNS, as well as more invasive surgical treatment options, and drugs for the treatment of OAB and FI. In addition, emerging businesses may be in the early stages of developing additional SNM devices or therapies designed to treat OAB or FI. Many of these companies have longer, more established operating histories and significantly greater financial, technical, marketing, sales, distribution and other resources than we do. We face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States. If one or more device manufacturers successfully develops a device that is more effective, better tolerated or otherwise results in a better patient experience, or if improvements in other third- line therapies make them more effective, easier to use or otherwise more attractive than our therapy, our ability to penetrate the third- line segment of the treatment market or maintain market share could be significantly and adversely affected, which would have a material adverse effect on our business, financial condition and results of operations. Bulkamid competes with bulking agents offered by Boston Scientific, Coloplast, and Laborie. Our overall competitive position is dependent upon a number of factors, including: • company, product, and brand recognition; • history of product use and physician familiarity with products and treatments; • regulatory approvals; • product safety, reliability and durability; • INS size, rechargeability and battery life; • quality and volume of clinical data; • effective marketing to and education of patients, physicians and hospitals; • product ease of use and patient comfort; • physician implantation and programming process; • sales force experience and market access; • product support and service; • technological innovation, product enhancements and speed of innovation; • pricing and revenue strategies; • procedure costs to patients and the overall healthcare system; and • dedicated practice development. In addition to existing competitors, other larger and more established companies may acquire or in- license competitive products and could directly compete with us. These competitors may also try to compete with our products on price both directly, through rebates and promotional programs to high volume physicians and coupons to patients, and indirectly, through attractive product bundling with complementary products that offer convenience and an effectively lower price compared to the total price of purchasing each product separately. Larger competitors may also be able to offer greater customer loyalty benefits to encourage repeat use of their products and finance a sustained global advertising campaign to compete with commercialization efforts of our SNM systems. Our competitors may seek to discredit our SNM systems by challenging our short operating history or relatively limited number of scientific studies and publications. Additionally, certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we could. See " Risks Related to Intellectual Property — Litigation or other proceedings or third- party claims of intellectual property infringement against us, including the Medtronic Litigation, or any of our current or future licensors, including AMF, could require us to spend significant time and money and could prevent us from selling our SNM systems, or affect our stock price. " Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. As more companies develop new intellectual property in our market, there is the possibility of a competitor acquiring patents or other rights that may limit our ability to update our technologies and products which may impact demand for our SNM systems. **AMF** ~~We rely solely on Contura International A / S as~~ **has alleged that Axonics is** a single source supplier to manufacture Bulkamid.....- party intellectual property rights could result in **material** ~~a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us. In addition, our reliance on Contura International entails additional risks, including reliance on Contura International for regulatory compliance and quality assurance, the possible~~ breach of ~~the Manufacturing and Supply Agreement by Contura International, and the possible termination of the Manufacturing and Supply Agreement at a time that is costly or inconvenient for us. Our failure, or the failure of Contura International, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of Bulkamid. Our dependence on Contura International also subjects us to all of the risks related to Contura International' s business, which are all generally beyond our control. Contura International' s ability to perform its obligations under the Manufacturing and Supply Agreement is dependent on Contura International' s operational and financial health, which could be negatively impacted by several factors, including changes in the economic and political and legislative conditions. Any termination or loss of significant rights under~~ the License Agreement ~~would materially~~ **because it is not paying royalties on its F15 product,** and ~~adversely affect our development and commercialization of our rechargeable SNM system. If~~ AMF **has claimed that it has** ~~terminates~~ **terminated** the License Agreement ~~under certain circumstances, we may be~~ **on that**

basis. The parties are in arbitration to resolve this dispute. Axonics strongly disagrees that it is required to pay ~~damages to~~ **royalties on the F15 product and that** AMF **has** ~~and AMF may have~~ the right to ~~terminate the license. In addition, if we do not have sufficient funds available to meet our payment obligations, AMF could~~ terminate the License Agreement. **Axonics has paid and will continue to pay 4 % royalties on rechargeable products and, pursuant to an interim agreement, is escrowing disputed amounts relating to its F15 system.** Any **effective** termination or loss of rights (including exclusivity) under the License Agreement **, or any resolution of the arbitration with AMF in a manner adverse to us,** could materially and adversely affect our ability to ~~develop and commercialize our rechargeable SNM system~~ **continue to sell products covered by the License Agreement** , which in turn would have a material adverse effect on our business, operating results and prospects ~~. If we are not successful in converting physicians and patients to our products, our business will not succeed~~ . For over 20 years, physicians and patients relied on the only other approved SNM therapy offered by Medtronic, InterStim II and its predecessor, InterStim I. As our SNM systems are relatively new products in the SNM market, our primary strategy to penetrate the market and grow our revenue is to drive physician and patient awareness of the material benefits of our SNM systems. Physicians and patients may choose not to adopt our SNM systems for a number of reasons, including: • familiarity or preference for current InterStim devices or new devices that Medtronic could develop and commercialize in the future; • lack of experience with our SNM systems and with SNM as a treatment alternative; • our inability to convince key opinion leaders to provide recommendations regarding our SNM systems, or to convince physicians and patients that it is an attractive alternative to InterStim devices and other third- line therapies such as BOTOX injections and PTNS; • perceived or actual benefits of InterStim devices; • perceived inadequacy of evidence supporting the clinical benefits or cost- effectiveness of our SNM systems over existing alternatives; • marketing and other efforts by Medtronic targeting physicians, including those with whom they have long- term relationships; and • ineffectiveness of our sales and marketing efforts for our SNM systems. In addition, patients may choose not to adopt SNM therapy as a potential therapy if, among other potential reasons, their anatomy would not allow for effective treatment with our SNM systems, they are reluctant to receive an implantable device as opposed to an alternative, non- implantable treatment, or they are worried about potential adverse effects of SNM therapy, such as infection, discomfort from the stimulation, or soreness or weakness. We believe that educating healthcare providers and patients about the clinical merits and patient benefits of our SNM systems as a treatment for OAB will be key elements driving adoption of our SNM therapies. However, some physicians may have prior history with or a preference for other treatment options. Moreover, our efforts to educate the medical community and patients on the benefits of our SNM systems will require significant resources **,** and we may never be successful. If healthcare providers and patients do not adopt our SNM systems, and our SNM systems do not achieve broad market acceptance, our ability to execute our growth strategy will be impaired, and our business and future prospects may be adversely affected. Our long- term growth substantially depends, in part, on our ability to enhance our products, and if we fail to do so we may be unable to compete effectively. It is important to our business and our long- term growth that we continue to ~~enhance our SNM systems. We intend to continue to~~ invest in research and development activities focused on ~~improvements and~~ enhancements to our SNM systems. Developing enhancements to our SNM systems can be expensive and time- consuming and ~~could~~ divert management' s attention away from the commercialization of our SNM systems and divert **our** financial resources **away** from other operations. The success of any new product enhancements will depend on several factors, including our ability to: • properly identify and anticipate physician and patient needs, and develop new product enhancements to meet those needs; • demonstrate, if required, the safety and effectiveness of new enhancements to our SNM systems with data from preclinical studies and clinical studies; • obtain, in a timely manner, the necessary regulatory clearances or approvals for new enhancements to our SNM systems, or product modifications for our SNM systems; • avoid infringing upon the intellectual property rights of third- parties; • be fully FDA- compliant with marketing of new devices or modified products; • address competitive counter moves advanced by Medtronic to secure and maintain customers; • develop an effective and dedicated sales and marketing team to provide adequate education and training to potential users ~~of~~ **regarding enhancements to** our SNM systems; and • receive adequate coverage and reimbursement for procedures performed with our **enhanced** SNM systems. If we are not successful in ~~commercializing our SNM systems and~~ developing and commercializing new product enhancements, our ability to achieve and maintain market share and increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations. If the quality of our products does not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected. In the course of conducting our business, we must adequately address quality issues that may arise with our products, including defects in third- party components included in our products. Although we have established internal procedures designed to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of our products ~~do~~ **does** not meet the expectations of physicians or patients. If the quality of our products does not meet the expectations of physicians or patients, then our brand ~~and~~ **,** reputation ~~with those physicians or patients~~ , ~~and our~~ business, financial condition and results of operations ~~,~~ could be adversely affected. The size and future growth in the market for SNM therapy and urethral bulking agents have not been established with precision and may be smaller than we estimate. If our estimates and projections overestimate the size of this market, our sales growth may be adversely affected. Our estimates of the size and future growth in the market for SNM therapy and urethral bulking agents, including the number of people in the United States and Europe with symptoms of either bladder or bowel dysfunction and who are readily treatable with **,** and eligible candidates for **,** our therapy, are based on a number of internal and third- party studies, reports and estimates. In addition, our internal estimates are based in large part on current treatment patterns by healthcare providers using our therapy and our belief that the incidence of bladder and bowel dysfunction in the United States, Europe and worldwide is increasing. While we believe these factors have historically provided **,** and may continue to provide us with **,** effective tools in estimating the total market for our therapy and our SNM systems, these estimates may not be correct and the conditions supporting our estimates may change

at any time, thereby reducing the predictive accuracy of these underlying factors. The actual numbers of people with bladder or bowel dysfunction who are readily treatable with **,** and eligible candidates for **,** our therapy, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. As a result, our estimates of the size and future growth in the market for our products may prove to be incorrect. If the actual number of people with bladder or bowel dysfunction who would benefit from our products and the size and future growth in the market for our products is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business. We may enter into collaborations, in- licensing arrangements, joint ventures, strategic alliances or partnerships with third- parties that may not result in the development of commercially viable products or product improvements or the generation of significant future revenues. In the ordinary course of our business, we may enter into collaborations, in- licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop new products or product improvements and to pursue new markets. Proposing, negotiating and implementing collaborations, in- licensing arrangements, joint ventures, strategic alliances or partnerships 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 viable product improvements or result in significant revenues 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 future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self- interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their 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 will be contractual in nature and will generally be terminable 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. If we enter into in- bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects. 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 harm our business, financial condition and operating results. From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including: • 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; • increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and • unanticipated or undisclosed liabilities of any target. 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 potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition. ~~Potential complications from our products or future enhancements to our products may not be revealed by our clinical experience.~~ Based on our experience, complications from use of our SNM systems may include infection, pain at site, lead migration or fracture, and the body' s rejection of the implant ~~.~~ **and** ~~Complications~~ **complications** ~~of~~ **from** the use of Bulkamid **may** include temporary pain, delayed urination, painful urination, and / or urinary tract infections. If unanticipated side ~~-~~effects result from the use of our products, we could be subject to liability and our device would not be widely adopted. Long- term use may result in unanticipated complications, even after the device is removed. Additionally, while the INS batteries for our SNM systems are designed to last approximately 15 to 20 years, we have not tested the battery in an actual implant in the body for that period and the battery may not last that long under normal or atypical use conditions. If implants in people reveal that our battery fails before its designed life, physicians and patients may lose confidence in our SNM systems, which may materially harm our reputation and our business ~~. If we fail to receive access to hospital facilities, our sales may decrease~~ . In the United States, in order for physicians to use our products, we expect that the hospital facilities where these physicians treat patients will typically require us to enter into purchasing contracts. This process can be lengthy and time- consuming and requires extensive negotiations and management time **, and may potentially result in delays before we can sell our products to these hospitals** .

In the EU, certain institutions may 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 hospital facilities 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. ~~Performance issues, service interruptions or price increases by shipping carriers could adversely affect our business and harm our reputation and ability to provide our products on a timely basis.~~ Expedited, reliable shipping **is** ~~will be~~ essential to our operations. We ~~intend to~~ rely heavily on providers of transport services for reliable and secure point- to- point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of our products, it would be costly to replace our products in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis. Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or ~~illegal activity~~ **other misconduct** . Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and non- U. S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and internationally or laws that require the true, complete and accurate reporting of financial **, billing and claims** information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations. Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products 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. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for ~~price~~ **pricing** 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 and ambulatory surgery centers (ASCs). We expect that market demand, government regulation, third- party coverage and 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 our products. To successfully market and sell our products in markets outside of the United States, we must address many international business risks with which we have limited experience, and failure to manage these risks may adversely affect our operating results and financial condition. We have sales and operations both inside and outside the United States, including a limited sales and marketing organization outside the United States. Our international sales strategy is to increase our presence in Europe, Canada, and Australia, which **we** have **initially** established ~~and favorable reimbursement~~ . With the purchase of Contura, we have greatly expanded our international operations through its direct sales force and distribution agreements **related to Bulkamid** . **Our** ~~International~~ **international** sales and operations are subject to a number of risks, including: • difficulties in staffing and managing our international sales, marketing, and other operations; • increased competition as a result of more products and procedures receiving regulatory approval or otherwise being free to market ~~in~~ internationally; • longer accounts receivable payment cycles and difficulties in collecting accounts receivable; • reduced or varied protection for intellectual property rights in some countries; • export restrictions, trade regulations, and foreign tax laws; • fluctuations in foreign currency exchange rates; • foreign certification and regulatory clearance or approval requirements; • difficulties in developing effective marketing campaigns in unfamiliar foreign countries; • customs clearance and shipping delays; • political, social, and economic instability internationally, **including as a result of armed conflict, war or the threat of war,** terrorist attacks, and security concerns in general **; • global health epidemics or other contagious diseases** ; • preference for locally manufactured products; • potentially adverse tax consequences, including the complexities of foreign value- added tax, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings; • the burdens of complying with a wide variety of foreign laws and different legal standards; • increased financial accounting and reporting burdens and complexities; and • **the burdens of complying with, and potential liability arising from, the** FCPA, Office of Foreign Assets Control (OFAC) **restrictions** , the Bribery Act, each of which is defined below, and other export

control, anti- corruption, anti- money laundering and anti- terrorism laws and regulations. If one or more of these risks are realized, our ability to expand our operations into international markets could be limited, which could adversely affect our business, financial condition and results of operations. Our ~~ability to maintain our competitive position will depend on our ability to retain senior management and other highly qualified personnel. Our~~ success ~~will depend~~ **depends** in part on our continued ability to **attract,** retain and motivate our highly qualified management, clinical, and other personnel. We are highly dependent upon our management team, particularly our Chief Executive Officer and member of our board of directors, Raymond W. Cohen, and the other members of our senior management, and other key personnel. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. The replacement of any of our key personnel **or other employees** would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives, which could have an adverse effect on our business. In addition, we do not carry any " key person " insurance policies that could offset potential loss of service under applicable circumstances. **Competition for experienced employees in the medical device industry can be intense. To attract, retain and motivate qualified employees, we may utilize equity- based incentive awards such as restricted stock units and employee stock options.** Many of our employees have become or will soon become vested in a meaningful amount of our common stock or common stock options. Our employees may be more likely to leave us if the shares they own or have the option to purchase have significantly appreciated in value relative to the original purchase price for the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. ~~Replacement~~ **Conversely, if the value** of ~~any~~ **such equity incentive awards does not appreciate as measured by the performance of the price of our common stock and ceases to be viewed as a valuable benefit, our ability to attract, retain, and motivate of** employees ~~who leave our company~~ could **be adversely impacted** ~~involve significant time and costs and may significantly delay or prevent the achievement of our business objectives~~, which could ~~have an adverse~~ **adversely** ~~effect~~ **affect our business, results of operations and financial condition and / or require us to increase the amount we expend** on ~~our business~~ **cash and other forms of compensation** . If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our products, our commercial success may be severely hindered, and in the event insurers require a prior authorization process, such process may not result in positive coverage determination for these patients. In the United States, we derive most of our revenue from the sale of our products to hospitals and ASCs, which typically bill various third- party payors, including Medicare, Medicaid, private insurance companies, health maintenance organizations and other healthcare- related organizations. In addition, we expect that any portion of the costs and fees associated with our products that are not covered by these third- party payors, such as deductibles or co- payments, will be billed directly to the patient by the provider. Further, certain third- party payors may not cover our products and the related procedures because they may determine that our products and the related procedures are experimental or investigational. Customers that perform the procedure may be subject to reimbursement claim denials upon submission of the claim. Customers may also be subject to recovery of overpayments if a third- party payor makes payment for the claim and subsequently determines that the third- party payor' s coding, billing or coverage policies were not followed. Further, any decline in the amount payors are willing to reimburse our customers could make it difficult for our customers to adopt or continue using our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business. Outside the United States, reimbursement levels vary significantly by country and by region, particularly based on whether the country or region at issue maintains a single- payor system. SNM therapy is eligible for reimbursement in Canada, Australia, and certain countries in the EU, such as Germany, France, and the United Kingdom. Annual healthcare budgets generally determine the number of SNM systems that will be paid for by the payor in these single- payor system countries and regions. Reimbursement is obtained from a variety of sources, including government- sponsored and private health insurance plans, and combinations of both. We intend to work with payors to obtain coverage and reimbursement approval in countries and regions where it makes economic sense to do so, however, we may not obtain such coverage, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business internationally ~~. We face the risk of product liability claims that could be expensive, divert management' s attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance~~ . Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future enhancements to our products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products could result in patient injury or death. The medical technology industry has historically been subject to extensive litigation over product liability claims, and we may face product liability suits. We may be subject to product liability claims if our products cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: • costs of litigation; • distraction of management' s attention from our primary business; • the inability to commercialize our products and develop enhancements to our products; • decreased demand for our products; • damage to our business reputation; • product recalls or withdrawals from the market; • withdrawal of clinical study participants; • substantial monetary awards to patients or other claimants; or • loss of sales. While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of

our products may delay the supply to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations. Although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. We bear the risk of warranty claims on our products. We bear the risk of warranty claims on our products. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or third- party manufacturers in the event of a successful warranty claim against us by a customer or and any recovery from any such supplier or third- party manufacturer could be inadequate. In addition, warranty claims brought by our customers related to third- party components may arise after our ability to bring corresponding warranty claims against such suppliers or third- party manufacturers expires, which could result in costs to us. ~~Failure of a key information technology system, process, or site could have an adverse effect on our business.~~ We rely extensively on information technology systems to conduct our business. These systems affect, among other things, ordering and managing materials from suppliers, shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security, and other processes necessary to manage our business. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate on a timely basis, we may experience interruptions in our operations, which could have an adverse effect on our business. ~~Furthermore, any breach in our information technology systems could lead to the unauthorized access, disclosure and use of non- public information, including information from our patient registry or other patient information, which is protected by HIPAA and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation.~~ If our facilities are damaged or become inoperable, we will be unable to continue to research and develop our products and, as a result, there will be an adverse effect on our business until we are able to secure a new facility and rebuild our inventory. We perform substantially all of our research and development and back- office activity and maintain a substantial portion of our finished goods inventory for our SNM systems in Irvine, California. We warehouse a substantially lesser quantity of finished goods in a contract warehousing facility in the Netherlands. Our facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. Our facilities, and those of our contractors, may be harmed or rendered inoperable by natural or man- made disasters, including, but not limited to, earthquakes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all. ~~Our results may be impacted by changes in foreign currency exchange rates. As our international sales increase, we may enter into a greater number of transactions denominated in non- U. S. dollars, which could expose us to foreign currency risks, including changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business could be harmed.~~ We are subject to anti- bribery, anti- corruption, and anti- money laundering laws, including the ~~U. S.~~ FCPA, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition. As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, EU, and other governments and organizations. The U. S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the FCPA and other federal statutes and regulations, including those established by the OFAC. In addition, the U. K. Bribery Act of 2010 (the Bribery Act) prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that " fails to prevent bribery " by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented " adequate procedures " to prevent bribery. Under these laws and regulations, as well as other anti- corruption laws, anti- money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations. We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti- corruption, anti- money- laundering and anti- terrorism laws and regulations. Our policies and procedures may not be

sufficient to ensure that our directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, or that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti- corruption, anti- money laundering and anti- terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations. Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain limitations. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an " ownership change, " generally defined as a greater than 50 % change by value in its equity ownership over a three- year period, is subject to limitations on its ability to utilize its pre- change net operating losses (NOLs) and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability. ~~A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the COVID- 19 virus, could adversely affect our business.~~ If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, SARS- CoV- 2, was identified in Wuhan, China. Since then, SARS- CoV- 2, and the resulting disease, COVID- 19, has spread to most countries and all 50 states within the United States. The COVID- 19 pandemic has negatively impacted our business, financial condition and results of operations by significantly decreasing and delaying the number of procedures performed using our SNM systems, and we expect the pandemic to continue to negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our SNM systems has decreased significantly as healthcare organizations in the United States and globally, including in Europe and Canada, have prioritized the treatment of patients with COVID- 19 or have altered their operations to prepare for and respond to the pandemic. For example, in the United States, governmental authorities have recommended, and in certain cases required, or healthcare providers have decided that elective, specialty and other procedures and appointments be suspended or canceled to avoid non- essential patient exposure to medical environments and potential infection with COVID- 19 and to focus limited resources and personnel capacity toward the treatment of COVID- 19 patients. We believe the COVID- 19 pandemic has also negatively impacted the number of OAB, FI and UR diagnoses and patients screened for eligibility for our SNM systems as hospitals and ASCs focus on COVID- 19 and as patients postpone healthcare visits and treatments. As 2021 and 2022 progressed, we observed a diminishing degree of COVID- related impacts to our reported revenue, although we believe there continues to be some adverse impact on our revenues. However, the extent to which the COVID- 19 pandemic continues to impact our results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and longevity of COVID- 19 and its variants, the resurgence of COVID- 19 in regions that have begun to recover from the initial impact of the pandemic, the impact of COVID- 19 on economic activity, and the actions to contain its impact on public health and the global economy. We believe this limited provider, hospital and ASC capacity could have a significant adverse effect on our business, financial condition and results of operations following the end of the pandemic. Additionally, even after it is deemed advisable to resume conducting elective procedures, some patients may elect not to undergo procedures or delay scheduling procedures to avoid traveling to healthcare facilities due to safety concerns. While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease, including COVID- 19, may be difficult to assess or predict, the widespread COVID- 19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID- 19, could materially affect our business. Such economic recession could have a material adverse effect on our long- term business as hospitals curtail and reduce capital and overall spending. In addition, the current economic downturn is resulting in significant job losses and reductions in disposable income and if patients are unable to obtain or maintain health insurance policies, this may significantly impact their ability to pay for the procedures utilizing our SNM systems, further negatively impacting our business, financial condition and results of operations. To the extent the COVID- 19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described herein, including those relating to incurring future operating losses, dependence on our SNM systems, successful commercialization, supply chain and distribution channels. The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results. There has been increasing public focus by investors, customers, environmental activists, the media, and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. We may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have an adverse impact on our business and financial condition. In addition, this emphasis on environmental, social and

other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted. ~~Risks Related~~ **We are increasingly dependent on our information technology systems and infrastructure for our business. We, our collaborators, and our service providers collect, store, and transmit sensitive information, including intellectual property, proprietary business information, clinical trial data, information from our patient registry or other patient information and personally identifiable information, in connection with our business operations. The secure maintenance of this information is critical** to ~~Legal Matters~~ **our operations and business strategy. Some of this information could be** ~~and~~ **an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, " hacktivists, " patient groups, disgruntled current or former employees, nation- state and nation- state supported actors, and others. Cyber- attacks are of ever- increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance. To date, these incidents have not materially affected our business. We have implemented information security measures to protect our systems, proprietary information, and sensitive data against the risk of inappropriate and unauthorized external use and disclosure and other types of compromise. However, despite these measures, and due to the constantly evolving cyber- risk landscape, we cannot guarantee that these measures will be adequate to identify, protect against, detect, respond to, and recover from security breaches and other incidents and we will not be subject to data breaches through cyber- attacks, malicious code (such as viruses and worms), phishing attacks, social engineering schemes, and insider theft or misuse. Any such breach could compromise our networks and any information stored in such networks could be accessed, modified, destroyed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion. Any security breach or other incident, whether real or perceived, could cause us to suffer reputational damage. Such incidents could result in costs to respond to, investigate and remedy such incidents, notification obligations to affected individuals,** ~~Government~~ **government** ~~Regulation~~ **agencies, credit reporting agencies and other third parties, legal claims or proceedings, liability under our contracts with other parties and liability or penalties under federal and state laws that protect the privacy and security of personally identifiable information. Any one of these events could cause our business to be materially harmed and our results of operations would be adversely impacted.** Our operations are subject to extensive government regulation and oversight both in the United States and internationally, and our failure to comply with applicable requirements could harm our business. We are subject to extensive, complex, costly and evolving regulation in the United States, the United Kingdom, the EU, Canada and other countries, including by the FDA and its foreign counterparts. With respect to medical devices, the FDA and foreign regulatory agencies regulate, among other things, design, development and manufacturing, testing, labeling, content and language of instructions for use and storage, clinical studies, product safety, establishment registration and device listing, marketing, sales and distribution, premarket clearance and approval, record keeping procedures, advertising and promotion, recalls and 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 approval studies, and product import and export. The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. Our failure to comply with all applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as warning letters, fines, injunctions, civil penalties, termination of distribution, recalls or seizures of products, delays in the introduction of products into the market, total or partial suspension of production, refusal to grant clearances or approvals, withdrawals or suspensions of approvals, prohibitions on sales of our products, and in the most serious cases, criminal penalties. We are also subject to the periodic scheduled or unscheduled inspection of our facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in costly remediation efforts, requirements that we complete government mandated clinical studies or government enforcement actions. The manufacturers that we work with are similarly subject to periodic scheduled or unscheduled inspections of their facilities. Adverse findings during such inspections may impact our inventory and cause disruptions in product sales. We may not receive the necessary clearances or approvals for modifications to our products or for future product candidates, and failure to timely obtain necessary clearances or approvals for modifications to our products or for future product candidates would adversely affect our ability to grow our business. As class III medical devices, our products, and our future product candidates, are and will be subject to the most stringent degree of medical device regulation. The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of medical device products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, with regulations differing from country to country. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based in part on extensive data, including, but not limited to, technical, pre- clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. In addition, a PMA generally requires the performance of one or more clinical studies. Despite the time, effort and cost, a device or modification may not be approved or cleared by the FDA. Any modifications to our products that were not previously approved may require us to submit an additional PMA or PMA supplement and obtain FDA approval prior to implementing the change. If the FDA requires us to go through a lengthier, more rigorous examination, make modifications to the device, or generate additional data to submit to the FDA, future product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: • inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that the device is safe or

effective for its intended uses; • the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of clinical studies or the interpretation of data from pre- clinical studies or clinical studies; • serious and unexpected adverse device effects experienced by participants in clinical studies; • the data from pre- clinical studies and clinical studies may be insufficient to support clearance or approval, where required; • inability to demonstrate that the clinical and other benefits of the device outweigh the risks; • the manufacturing process or facilities may not meet applicable requirements; and • the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering clinical data or regulatory filings insufficient for clearance or approval. The FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may impact our ability to modify our products or introduce future products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain approvals once obtained. In order to sell our products in member countries of the EEA (which is composed of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein), it must comply with the essential requirements of the EU Active Implantable Medical Devices Directive (Council Directive 90 / 385 / EEC) (the AIMD Directive). If any future product candidates are also considered to qualify as an active implantable medical device, or AIMD, under the AIMD Directive, it too will need to comply with the essential requirements it sets out. Alternatively, if a future product candidate is not considered an AIMD under the AIMD Directive, it will still be required to comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93 / 42 / EEC). The Medical Devices Regulations (Regulation 2017 / 745) are also now in force, as further discussed below. Compliance with the requirements under either of these Directives and confirmation of compliance by a Notified Body are prerequisites to affixing the CE mark to our rechargeable SNM system and any future product candidates. Without a CE mark, medical devices cannot be sold or marketed in the EEA. To demonstrate that our rechargeable SNM system is compliant with the essential requirements set out under the AIMD Directive, we must undergo a conformity assessment procedure. This requires an assessment of available clinical evidence, literature data for the product and post- market experience in respect of similar products already marketed to ensure and declare that the products in question comply with the standards set out in Annex I of the AIMD Directive. In addition, a conformity assessment procedure requires the intervention of a Notified Body. Notified Bodies are separate entities that are authorized or licensed to perform such assessments by the governmental authorities of each EU Member State. Manufacturers of AIMDs must make an application to a Notified Body for an assessment of its technical dossiers and quality system. Alternatively, manufacturers can seek approval from the Notified Body that a representative sample of the products it has manufactured satisfies the requirements set out in the AIMD Directive and subsequently ensure and declare that all of its products conform to the standard of the approved sample. This is also known as " type approval. " Future product candidates that are not considered AIMDs under the AIMD Directive will still require a conformity assessment procedure. The types of procedures required are set out in the Medical Devices Directive and will vary according to the type of medical device and its classification. For low- risk medical devices (Class I non- sterile, non- measuring devices) the manufacturer can issue a Declaration of Conformity based on a self- assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive. However, for all other types of medical devices a similar conformity assessment procedure to that outlined above and in the AIMD Directive will be required, also involving the intervention of a Notified Body. For our products, future AIMD product candidates and all other future product candidates, the Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, 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 are supported by suitable evidence. If we fail to remain in compliance with the applicable Directives outlined above, we would be unable to continue to affix the CE mark to our rechargeable SNM system or our external trial system, which would prevent us from selling it within the EEA. ~~Modifications to our products may require us to obtain new PMA approvals or approvals of a PMA supplement, and if we market modified products without obtaining necessary approvals, we may be required to cease marketing or recall the modified products until required approvals are obtained. Certain modifications to a PMA- approved device may require approval of a new PMA or a PMA supplement, or alternatively a notification or other submission to FDA. We will be responsible for deciding whether a modification requires approval by the FDA. However, the FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our products that we believe do not require approval of a new PMA or PMA supplement. If the FDA disagrees with our determination and requires us to submit a new PMA or PMA supplement for modifications to previously approved products, we may be required to cease marketing or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. Any delay or failure in obtaining required approvals would adversely affect our ability to introduce enhanced products in a timely manner, which in turn would harm our future growth.~~ The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about approved medical devices, such as our products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or other similar regulatory authorities as reflected in the product' s

approved labeling. Physicians could use our products on their patients in a manner that is inconsistent with the approved label. We cannot prevent a physician from using our products off- label when in the physician' s independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off- label. Furthermore, the use of our products for indications other than those that may be approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. If the FDA or any foreign regulatory body 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 or imposition of a warning letter, an untitled letter, which is used for violators that do not necessitate 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 under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages (including treble damages), fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. In addition, physicians may misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to an increased risk of product liability claims. If our products are misused or used with improper techniques or are determined to cause or contribute to patient harm, we may become subject to costly litigation by our customers or patients. The clinical study process required to obtain regulatory approvals is lengthy and expensive with uncertain outcomes. If clinical studies of our products do not produce results necessary to support regulatory clearance or approval in the United States or elsewhere, we will be unable to expand the indications for our products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of our products. In order to obtain approval for a PMA or PMA supplement for expanded indications, the sponsor must meet the regulatory submission requirements of the FDA, which in many cases may require a PMA applicant to conduct well- controlled clinical studies designed to assess the safety and effectiveness of the product. Conducting clinical studies is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical studies but cannot be certain that the trials will ever result in commercial revenue. We may experience significant setbacks in clinical studies, even after earlier clinical studies showed promising results, and failure can occur at any time during the clinical study process. A device could malfunction or produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical studies. We, the FDA, an Institutional Review Board (IRB) or another regulatory authority may suspend or terminate clinical studies at any time to avoid exposing trial participants to unacceptable health risks. Successful results of pre- clinical studies are not necessarily indicative of future clinical study results, and predecessor clinical study results may not be replicated in subsequent clinical studies. Additionally, the FDA may disagree with our interpretation of the data from our pre- clinical studies and clinical studies, or may find the clinical study design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre- clinical studies or clinical studies. In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include obtaining the right to affix the CE mark to certain products in the EU, submitting an IDE to the FDA, applying to commence a pivotal clinical study for a new product, enrolling patients in clinical studies, releasing data from clinical studies, and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates and public announcements, in some cases for reasons beyond our control. Clinical studies are necessary to support PMA applications and may be necessary to support PMA supplements for modified versions of our products. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. Adverse outcomes in the post- approval studies could also result in restrictions or withdrawal of a PMA approval. We may need to conduct additional clinical studies in the future for the approval of the use of our products in some foreign countries. Clinical testing is difficult to design and implement, can take many years, can be expensive, and, testing carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. We may experience a number of events that could adversely affect the costs, timing or successful completion of our clinical studies, including: • we may be required to submit an IDE application to FDA, which must become effective prior to commencing human clinical studies, and the FDA may reject our IDE application and notify us that we may not begin investigational trials; • regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies; • regulators and / or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical study at a prospective or specific trial site for various reasons, including safety signals or noncompliance with regulatory requirements; • we may not reach agreements with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs; • the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical studies at a higher rate than we anticipate; • our third- party manufacturers, including those conducting clinical studies on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we might have to suspend or terminate clinical studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks; • we may have to amend clinical study protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and / or regulatory authorities for re- examination; • the cost of clinical

studies may be greater than we anticipate; • clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial; • we may be unable to recruit a sufficient number of clinical study sites; • regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third- party manufacturers or suppliers of materials for our clinical studies, the materials necessary to conduct clinical studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; • approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and • our products or other product candidates may have undesirable side effects or other unexpected characteristics. Patient enrollment in clinical studies and completion of patient follow- up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. In addition, patients participating in our clinical studies may drop out before completion of the trial or experience adverse medical events unrelated to the device. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial, or result in the failure of the clinical trial. Clinical studies must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with supplies of our product produced under cGMP requirements and other regulations. Furthermore, we rely on clinical study sites to ensure the proper and timely conduct of our clinical studies and we have limited influence over their performance. We depend on our collaborators and on medical institutions and employees to conduct our clinical studies in compliance with good clinical practice (GCP) requirements. If our collaborators fail to enroll participants for our clinical studies, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical studies that are conducted in countries outside the United States may result in additional delays and expenses due to increased shipment costs, additional regulatory requirements and the engagement of non- U. S. resources, and may expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non- clinical testing in addition to those we have planned. Our failure to adequately demonstrate the safety and effectiveness of any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, limit our ability to commercialize the product. ~~Failure to comply with post- market regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw our products from the market.~~ We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, registration, and listing of our products. For example, we are required to submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. We have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions: • untitled letters or warning letters; • fines, injunctions, consent decrees and civil penalties; • recalls, termination of distribution, administrative detention, or seizure of our products; • customer notifications or repair, replacement or refunds; • operating restrictions or partial suspension or total shutdown of production; • delays in or refusal to grant future PMA approvals or foreign regulatory approvals of future product candidates, new intended uses, or modifications to our existing product; • withdrawals or suspensions of PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products; • FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and • criminal prosecution. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. Our products must be manufactured in accordance with federal and state regulations, and we or any of our suppliers or third- party manufacturers could be forced to recall our products or terminate production if we fail to comply with these regulations. The methods used in, and the facilities used for, the manufacture of our products must comply with the QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing. Our third- party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products or result in it being adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with the manufacturing processes for our products could result in, among other things: warning letters or untitled letters, fines, injunctions or civil penalties, suspension or withdrawal of approvals, seizures or recalls of our

products, total or partial suspension of production or distribution, administrative or judicially imposed sanctions, the FDA' s refusal to grant pending or future clearances or approvals, clinical holds, refusal to permit the import or export of our products, and criminal prosecution of us or our employees. Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs ~~. If treatment guidelines for OAB, SUI, FI or UR change or the standard of care evolves, we may need to redesign and seek a new marketing authorization from the FDA for our products~~ . If treatment guidelines for OAB, SUI, FI or UR change or the standard of care evolves, we may need to redesign our products, or any future product, and seek new approvals from the FDA. PMA approvals from the FDA are based on current treatment guidelines at the time of the approvals. If treatment guidelines change so that different treatments become desirable, the clinical utility of our products could be diminished and our business could be adversely affected. 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 if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. We are subject to the FDA' s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. 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 could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of device approvals, seizure of our products or delay in clearance or approval of modifications to our products. The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that our products could cause serious injury or death. We may also choose to voluntarily recall our products if any material deficiency is found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Defects or other errors in our products may occur in the future. Depending on the corrective action we take to redress deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals for our products 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 products, we may face additional regulatory enforcement action, 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 may 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 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 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. Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our products, a number of potentially negative consequences could result, including: • regulatory authorities may withdraw their approval of the product; • regulatory authorities may require a recall of the product or we may voluntarily recall a product; • regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or issuance of field alerts to physicians and pharmacies; • regulatory authorities may require us to create a guide outlining the risks of such side effects for distribution to patients; • we may be subject to limitations as to how we promote the product; • we may be required to change the way the product is administered or modify the product in some other way; • regulatory authorities may require additional clinical studies or costly post- marketing testing and surveillance to monitor the safety or efficacy of the product; • sales of the product may decrease significantly; • we could be sued and held liable for harm caused to patients; and • our brand and reputation may suffer. Any of the above events could prevent us from achieving or maintaining market acceptance of our products and could substantially increase the costs of commercializing our products. The demand for our products could also be negatively impacted by any adverse effects of a competitor' s product or treatment. Legislative or regulatory reforms in the United States or Europe may make it more difficult and costly for us to obtain regulatory clearances or approvals for modifications to our products, or to manufacture, market or distribute our products. From time to time, legislation is drafted and introduced in U. S. Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times, or make it more difficult to obtain approval for additional indications for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval for future product candidates, changes to manufacturing methods, recall, replacement or discontinuance of future product candidates, or additional record keeping. We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws

and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws 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 may also be 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. The healthcare laws and regulations 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, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid; • the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent; • 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 beneficiary' s decision to order or receive items or services reimbursable by the government from a particular provider or supplier; • HIPAA which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters; • the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which requires reports annually to the CMS information related to payments and other transfers of value to physicians; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) 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; • analogous state and foreign law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the applicable 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; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers; and • state laws related to insurance fraud in the case of claims involving private insurers. 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. To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional 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. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and responding to any such challenge or investigation would be costly and divert the attention of our management. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations. We may be subject to, or may in the future become subject to, U. S. federal and state, and foreign laws and regulations imposing obligations on how we collect, store and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue. As described above, in the conduct of our business, we may at times process personal data, including health- related personal data. The U. S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U. S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. State privacy and security laws vary from state to state and, in some cases, can impose more restrictive requirements than U. S. federal law. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for misuse of personal information. The EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, which are often more restrictive than those in the United States and which restrict transfers of personal data to the United States unless certain requirements are met. These obligations may be interpreted and applied in a

manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. Any actual or perceived failure by us or the third parties with whom we work to comply with privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of personally identifiable information, may result in governmental enforcement actions and investigations including by European Data Protection Authorities and U. S. federal and state regulatory authorities, fines and penalties, litigation and / or adverse publicity, including by consumer advocacy groups, and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations. Our business involves the use of hazardous materials and our third- party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business. Our third- party manufacturers' activities may involve the controlled storage, use and disposal of hazardous materials. Our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe the safety procedures of our manufacturers for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our manufacturers' use of these materials and interrupt their business operations which could adversely affect our business. Compliance with securities rules relating to " conflict minerals " may require us and our suppliers to incur substantial expense and may result in disclosure by us that certain minerals used in products we manufacture or contract to manufacture are not " DRC conflict free. " Because we manufacture or contract to manufacture a product that contains titanium, we may be required under rules promulgated by the SEC governing disclosure of the use of " conflict minerals " (tin, tungsten, tantalum and gold) to determine whether those minerals are necessary to the functionality or production of our SNM systems and, if so, conduct a country of origin inquiry with respect to all such minerals. If any such minerals may have originated in the Democratic Republic of the Congo (DRC) or any of its adjoining countries, or covered countries, then we must conduct diligence on the source and chain of custody of those conflict minerals to determine if they originated in one of the covered countries and, if so, whether they financed or benefited armed groups in the covered countries. Disclosures relating to the products that may contain conflict minerals, the country of origin of those minerals and whether they are " DRC conflict free " must be provided in a Form SD (and accompanying conflict minerals report, if required, to disclose the diligence undertaken by us in sourcing the minerals and our conclusions relating to such diligence). If we are required to submit a conflict minerals report, that report must be audited by an independent auditor pursuant to existing government auditing standards. Compliance with this disclosure rule may be very time- consuming for our management and personnel (as well as time- consuming for our suppliers) and could involve the expenditure of significant amounts of money by us and them. Disclosures mandated by this rule, which can be perceived by the market to be " negative, " may cause customers to refuse to purchase our SNM systems. The cost of compliance with the rule could adversely affect our results of operations. We depend upon third- party suppliers, including single source component suppliers, making us vulnerable to supply problems, which could lead to requiring new regulatory approvals in order to make component or supplier changes. We rely on third- party suppliers, including some single source suppliers for certain components of our products, to provide us with a portion of our demand for one of our products as well as components used in the manufacturing of our products. In some cases, we purchase supplies through purchase orders and do not have long- term supply agreements with, or guaranteed commitments from, our component suppliers, including single source suppliers. Many of our suppliers and contract manufacturers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers to provide us and our customers with materials or products in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, ~~including as a result of the ongoing COVID- 19 pandemic,~~ any of which could delay or impede their ability to meet our demand. These suppliers may cease producing the products or components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. In addition, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe alternate suppliers exist for all materials, components and services necessary to manufacture our products, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time- consuming, expensive and may result in interruptions in our operations and product delivery. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay or which may not be obtained at all. If our third- party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost, volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations. Litigation or other proceedings or third- party claims of intellectual property infringement against us, including the Medtronic Litigation, or any of our current or future licensors, including AMF, could require us to spend significant time and money and could prevent us from selling our products, or affect our stock price. Our commercial success will depend in part on our ability to avoid infringement of the proprietary rights of third parties. To the extent that our commercial partners, collaborators, employees and consultants use

intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. Our competitors in both the United States and internationally, many of which have substantially greater resources, and, may 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 and sell our products. We do not always conduct independent reviews of patents issued to third parties. Because we have not conducted a formal freedom to operate analysis for patents related to our products, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our products. Even in the event that we conduct a formal freedom to operate analysis, patent searches to determine whether our products infringe patents held by third parties are inherently uncertain and such searches cannot assure that all relevant patents are identified. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications for other patents now pending or recently revived patents of which we are unaware that our products may infringe. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the technology and medical device industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination or review proceedings before the U. S. Patent and Trademark Office. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our products or will develop future product candidates. As the technology and medical device industries expand and more patents are issued, the risk continues, or possibly increases, that our products may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we, or any of our current or future licensors, including AMF, are employing their proprietary technology without authorization. For example, on November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (collectively, the Medtronic Affiliates) filed a complaint against us in the U. S. District Court for the Central District of California, Case No. 8: 19- cv- 2115, and amended the complaint on November 26, 2019. We refer to this matter as the Medtronic Litigation. The complaint asserts that our rechargeable SNM system infringes U. S. Patent Nos. 8, 036, 756, 8, 626, 314, 9, 463, 324 and 9, 821, 112 held by the Medtronic Affiliates, and the amended complaint further includes the additional patents 8, 738, 148; 8, 457, 758; and 7, 774, 069 (collectively, the Medtronic Patents). The Medtronic Litigation requests customary remedies for patent infringement, including (i) a judgment that we have infringed and are infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) a permanent injunction preventing us from infringing the Medtronic Patents, (iv) attorneys' fees, and (v) costs and expenses. **The Federal Circuit recently reversed the decision of the Patent Trials & Appeals Board of the U. S. Patent & Trademark Office (PTAB) that the tined leads patents asserted against us were valid, finding that the PTAB committed legal error in its analysis. The Federal Circuit remanded the matter to the PTAB for another review consistent with its opinion. Because of this development, the U. S. District Court has issued a stay on the litigation proceedings, pending the outcome of the proceedings before the PTAB. As a result, the jury trial previously scheduled for August 2023 has been postponed. The Federal Circuit also recently vacated the decision of the PTAB that certain claims of Patent Nos. 8, 738, 148 and 8, 457, 758 had not been shown to be invalid and the Federal Circuit remanded these matters for further proceedings before the PTAB.** We believe the allegations **of the Medtronic Affiliates** are without merit and are vigorously defending ourselves against them. We are unable to predict the likelihood of success of the claims of the Medtronic Affiliates against us or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and require us to dedicate significant financial resources and management resources to our defense. An adverse ruling against us could materially and adversely affect our business, financial position, results of operations or cash flows and could also result in reputational harm. Even if we are successful in defending against these claims, the Medtronic Litigation could result in significant costs, delays in future product developments, reputational harm or other collateral consequences ~~. The Company is currently engaged in discovery in the Medtronic Litigation. A jury trial is scheduled in the Medtronic Litigation for April 2023~~ . Defense of any of the above claims, including the Medtronic Litigation, would require us to dedicate substantial time and resources, which time and resources could otherwise be used by us toward the maintenance of our own intellectual property and the commercialization of our products, or by any of our current or future licensors for operational upkeep and manufacturing of our products. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time- consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following: • stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property; • lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; • incur significant legal expenses; • pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing; • pay the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; • redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive, or infeasible; and • attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms, or at all, or, from third parties ~~whom~~ **who** may attempt to license rights that they have or do not have. Any litigation or claim against us or AMF, 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 commercialization of our SNM systems, or harm our reputation. If we or AMF are found to infringe the

intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and / or substantial royalties and could be prevented from selling our infringing products unless we obtain a license or are able to redesign our SNM systems to avoid infringement. Any such license may not be available on reasonable terms, if at all, and we may not be able to redesign the infringing product in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our SNM systems, including future technologies, we may have to withdraw our SNM systems from the market or may be unable to commercialize our SNM systems. In addition, third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or indemnify our customers for any costs associated with their own initiation or defense of infringement claims, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers 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. ~~If we or any of our current or future licensors, including AMF, are unable to maintain, obtain or adequately protect our intellectual property rights, we may not be able to compete effectively in our market or we could be required to incur significant expenses to enforce or defend our rights or attempt to do the same.~~ Our commercial success depends in part on ours and any of our current or future licensors', including AMF' s, success in obtaining, maintaining and protecting patents, trademarks, trade secrets and other intellectual property rights and proprietary technology in the United States and elsewhere. If we or any of our current or future licensors, including AMF, do not adequately protect our respective intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. Our intellectual property coverage includes protection provided by patents and other intellectual property licensed through the License Agreement with AMF. We rely on AMF to maintain the patents and otherwise protect the intellectual property we license from them. **As addressed above, AMF has alleged that Axonics is in material breach of the License Agreement because it is not paying royalties on its F15 product, and AMF has claimed that it has terminated the License Agreement on that basis. The parties are in arbitration to resolve this dispute.** If in the future **,** we no longer have rights to one or more of these licensed patents or other licensed intellectual property, our intellectual property coverage may be compromised, which in turn could affect our ability to protect our rechargeable SNM system and defend it against competitors. Our patents may not have, and any of our pending patent applications that mature into issued patents may not include, claims with a scope sufficient to adequately protect our products, or any additional features we develop for our products or any new products. Other parties may have developed technologies that may be related to or competitive with our products, and, may have filed, or may file, patent applications, and, may have received, or may receive patents, that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent, or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to commercialize our products. Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, circumvent or design around our patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. In addition, third parties may create new products or methods that achieve similar results without infringing upon patents we own. If these developments were to occur, it could have an adverse effect on our sales or market position. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. In addition, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product. We may not prevail in some, or any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time- consuming and could divert the attention of our management and key personnel from our business operations. In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some, or all, of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or, if a court found that valid, enforceable patents held by third parties covered our products, our competitive position could be harmed, or, we could be required to incur significant expenses to enforce or defend our rights. In addition, we rely in part upon unpatented trade secrets, unpatented know- how, and continuing technological innovation which may not yet, or may never be, patented, to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and consultants. We also have agreements with our employees and consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a

person that is not a party to such an agreement. In addition, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. Further, our trade secrets could otherwise become known or be independently discovered by our competitors, which would harm our business. We are reliant on the ability of AMF, as licensor of certain intellectual property contained in our products, and may be reliant on, future licensors to maintain their intellectual property and protect their intellectual property against misappropriation, infringement or other violation. In some instances, we may not have primary control over AMF' s, or our other future licensors', patent prosecution activities. With respect to licensed patents that were issued to our licensors, or patents that may issue on patent applications, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. As a licensee, we are reliant on AMF to defend any third- party claims or consent to our defending them on their behalf. Our licensors may not defend or prosecute such actions as vigorously or in the manner that we would have if entitled to do so, and we will be subject to any judgment or settlement resulting from such actions and our business could be adversely affected. If we are unable to protect the confidentiality of our trade secrets, our business or competitive position could be harmed. In addition to patent protection, we also rely upon other non- patent protection, such as: trademark, or, trade secret protection, as well as confidentiality agreements with our employees, consultants, vendors, and third parties, to protect our confidential and proprietary information. Despite the existence of such confidentiality agreements, or other contractual restrictions, we may not be able to prevent the unauthorized disclosure or use of our confidential proprietary information or trade secrets by employees, consultants, vendors, and third parties. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and, recourse we take against such misconduct may not provide an adequate remedy to fully protect our interests. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed, or misappropriated a trade secret, can be difficult, expensive and time- consuming, and, the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. Furthermore, the laws of foreign countries may not protect our trade secrets effectively or to the same extent as the laws of the United States. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed. We may be unable to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. If we face similar challenges with respect to material intellectual property matters, this could make it difficult for us to stop infringement of our foreign patents or our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Litigation may be necessary in the future to enforce our intellectual property rights or protect our trade secrets or other proprietary information, which is an expensive and time- consuming process with uncertain outcomes. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from the commercialization of our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. Third parties may ~~assert ownership or commercial rights to inventions we develop. Third parties may~~ , in the future, make claims challenging the inventorship or ownership of our intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or we may lose our rights in that intellectual property. Either outcome could harm our business and competitive position. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who previously worked with other companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information, including trade secrets or other proprietary information, of former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Any litigation or the threat thereof may adversely

affect our ability to hire employees and we may lose valuable intellectual property rights if we fail in defending any such claims. A loss of key personnel or their work product could diminish or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition. ~~If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.~~ We are a party to the License Agreement with AMF and we may be a party to future license agreements. One or more of our licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license. If successful, this could result in our loss of the right to use the licensed intellectual property, which could adversely affect our ability to commercialize our products, as well as harm our competitive business position and our business prospects. In particular, the License Agreement imposes various development, royalty, insurance and other obligations on us. If we fail to comply with these obligations or otherwise materially breach the License Agreement, AMF may have the right to terminate the License Agreement, in which event we would not be able to market our products. ~~In addition~~ **As addressed above** , **AMF has alleged that Axonics is in material breach of the License Agreement because it is not paying royalties on its F15 product, and AMF has claimed that it has terminated the License Agreement on that basis. The parties are in arbitration to resolve this dispute. Such arbitration and** any **future** claims asserted against us by AMF may be costly and time- consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business. ~~Risks Related~~ **In addition, any effective termination or loss of rights (including exclusivity) under the License Agreement could materially and adversely affect our ability** to ~~Our Common Stock~~ **continue to sell products covered by the License Agreement, which in turn would have a material adverse effect on our business, operating results and prospects.** The trading price of our common stock may be volatile, and purchasers of our common stock could incur substantial losses. Our stock price may be volatile. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, some of which are beyond our control, including: **• the timing of, and our ability to close, the merger with Boston Scientific, including any changes in factors that influence the timing and likelihood of the closing of the Merger, as well as market reactions to the proposed Merger with Boston Scientific; • any developments related to the business of Boston Scientific, including during the pendency of the Merger;** • the impact of worldwide pandemics on voluntary surgical procedures; • unanticipated safety concerns related to the use of our products; • FDA or other U. S. or foreign regulatory or legal actions or changes affecting us or our industry; • intellectual property, product liability or other litigation against us, our third- party manufacturers or other parties on which we rely or litigation against our general industry; • any termination or loss of rights under the License Agreement; • any voluntary or regulatory mandated product recalls; • adverse developments concerning our manufacturers or suppliers or any future strategic partnerships; • introductions and announcements of new technologies by us, any commercialization partners or our competitors, and the timing of these introductions and announcements; • announcements of regulatory approval or disapproval of our products or for any future enhancements to our products; • adverse results from or delays in clinical studies of our products; • our ability to successfully integrate acquired operations into our ongoing business; • variations in our financial results or those of companies that are perceived to be similar to us; • success or failure of competitive products or therapies in the SNM market; • changes in the structure of healthcare payment of our products; • announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments; • market conditions in the medical technology industry and issuance of securities analysts' reports or recommendations; • quarterly variations in our results of operations or those of our competitors; • changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance; • the public' s reaction to our earnings releases, other public announcements and filings with the SEC; • rumors and market speculation involving us or other companies in our industry; • sales of substantial amounts of our stock by directors, officers or significant stockholders, or the expectation that such sales might occur; • general economic, industry and market conditions, including the size and growth, if any, of the market; • news reports relating to trends, concerns and other issues in the market or industry; • operating and stock performance of other companies that investors deem comparable to us and overall performance of the equity markets; • additions or departures of key personnel; • changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; • changes in accounting standards, policies, guidelines, interpretations or principles; • the results of any future legal proceedings; and • other factors described in this " Risk Factors " section. In addition, in the past, stockholders have initiated class action lawsuits against companies following periods of volatility in the market prices of these companies' common stock. Such litigation, if instituted against us, regardless of the merit or ultimate results of such litigation, could cause us to incur substantial costs and divert management' s attention and resources. We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in us, and, as a result, the value of our common stock. To comply with the requirements of being a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes- Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. Further, the Sarbanes- Oxley Act also requires that our internal control over financial reporting be attested to by our independent registered public accounting firm. **We have had in the past, and may have in the future, material weaknesses and significant deficiencies in our internal control over financial reporting.** If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. The process of designing and implementing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting are effective, or if our

independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on Nasdaq ~~. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud~~ . We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities. Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. Anti- takeover provisions in our certificate of incorporation and bylaws, as well as under Delaware law, could discourage a takeover. Provisions in our certificate of incorporation and our bylaws 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 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; • require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent; • 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 acquiror' s own slate of directors or otherwise attempting to obtain control of ~~our~~ **the** ~~company~~ **Company** ; • prohibit cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; and • provide that special meetings of our stockholders may be called only by the Chair of the board, our Chief Executive Officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, which may delay the ability of our stockholders to force consideration by ~~our~~ **the** ~~company~~ **Company** of a take- over proposal or to take certain corporate actions, including the removal of directors. In addition, Section 203 of the Delaware General Corporation Law (DGCL) which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This provision could have the effect of delaying or preventing a change in control of ~~our~~ **the** ~~company~~ **Company** , whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us. Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us

or our directors, officers, employees or agents. Our certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws, any action asserting a claim that is governed by the internal affairs doctrine and the resolution of any complaint asserting a cause of action arising under the Securities Act, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein and the claim not being one which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or for which the Court of Chancery does not have subject matter jurisdiction. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to these provisions of our certificate of incorporation. These choice of forum provisions may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations. ~~If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.~~ The trading market for our common stock will rely in part on the research and reports that securities or industry analysts publish about us and our business. If one or more of the analysts who cover us downgrades our common stock or issues other unfavorable commentary or research the price of our common stock may decline. If one or more analysts ceases coverage of ~~our~~ **the** ~~company~~ **Company** or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline and could result in the loss of all or part of your investment in us. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future, so capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.