UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-38721

Axonics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-4744083**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
26 Technology Drive **Irvine, California**	**92618**
(Address of principal executive offices)	**(Zip Code)**

(949) 396-6322

(Registrant's telephone number, including area code)

Title of class	**Trading symbol**	**Name of exchange on which registered**
Common stock, par value $0.0001 per share	AXNX	Nasdaq Global Select Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $2.5 billion, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $50.47 per share for such date.

As of February 26, 2024, 51,003,429 shares of the registrant's common stock, par value $0.0001 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information that is required to be included in Part III of this Annual Report on Form 10-K is incorporated by reference to either a definitive proxy statement or an amendment to this Annual Report on Form 10-K to be filed by the registrant within 120 days of December 31, 2023. Only those portions of any such definitive proxy statement that are specifically incorporated by reference herein shall constitute a part of this Annual Report on Form 10-K.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), that involve risks and uncertainties, including statements based on our current expectations, assumptions, estimates and projections about future events, our business, financial condition, results of operations and prospects, our industry and the regulatory environment in which we operate. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, or other comparable terms intended to identify statements about the future. Forward-looking statements include, but are not limited to, statements about:

- our ability to consummate the Merger with Boston Scientific (as each such term is defined under Item 1 "Business" of Part I of this Annual Report on Form 10-K) announced on January 8, 2024, in a timely manner or at all;
- the risk that the Merger Agreement (as defined under Item 1 "Business" of Part I of this Annual Report on Form 10-K) may be terminated in circumstances that require us to pay a $75 million termination fee to Boston Scientific;
- the satisfaction (or waiver) of the conditions to the closing of the Merger, including with respect to the approval of our stockholders and approvals under applicable antitrust laws;
- potential delays in consummating the Merger;
- our ability to timely and successfully achieve the anticipated benefits of the Merger;
- the risk related to the diversion of management's attention from our ongoing business operations as a result of the Merger;
- the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Merger Agreement;
- the effect of the announcement or pendency of the Merger on our business relationships, operating results and business generally;
- the risk that the Merger disrupts our current plans and operations or affects our ability to retain or recruit key employees;
- costs related to the Merger;
- the effect of limitations that the Merger Agreement places on our ability to operate our business or engage in an alternate transaction;
- the risk that our stock price may decline significantly if the Merger is not completed;
- unanticipated safety concerns related to the use of our products;
- U.S. Food and Drug Administration (FDA) or other U.S. or foreign regulatory or legal actions or changes affecting us or our industry;
- the results of any ongoing or future legal proceedings, including, but not limited to, in relation to the Merger or Merger Agreement, intellectual property, or 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 intellectual property rights, including as a result of the Medtronic Litigation (as defined under Item 1A "Risk Factors" of Part I of this Annual Report on Form 10-K);
- any voluntary or regulatory mandated product recalls;
- adverse developments concerning our manufacturers or suppliers or any future strategic partnerships;

- reduction or interruption in our supply chain and other possible inventory constraints or challenges;
- introductions and announcements of new technologies by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- successful integration of acquired operations into our ongoing business;
- announcements of regulatory approval or disapproval of our products and any future enhancements to our products;
- adverse results from or delays in clinical studies of our products;
- 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 markets in which we do business;
- changes in the structure of healthcare payments for our products;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- changes in macroeconomic and market conditions and volatility, including the risk of recession, inflation, supply chain constraints or disruptions and rising interest rates;
- economic and market conditions in general and in the medical technology industry specifically, including the size and growth, if any, of our markets, and the issuance of securities analysts' reports or recommendations;
- 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;
- additions or departures of key personnel; and
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt.

The forward-looking statements included herein are based on current expectations of our management based on available information and involve a number of risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond our control. As such, our actual results may differ significantly from those expressed in any forward-looking statements. Factors that may cause or contribute to such differences include, but are not limited to, those discussed in more detail in Item 1 "Business" and Item 1A "Risk Factors" of Part I and Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of Part II of this Annual Report on Form 10-K. Readers should carefully review these risks, as well as the additional risks described in other documents we file from time to time with the Securities and Exchange Commission (SEC). In light of the significant risks and uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that such results will be achieved, and readers are cautioned not to place undue reliance on such forward-looking statements. Except as required by law, we undertake no obligation to revise the forward-looking statements contained herein to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. You should read this Annual Report on Form 10-K and the documents we file with the SEC, with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Unless the context indicates otherwise, as used in this Annual Report on Form 10-K, the terms "Axonics," the "Company," "we," "us" and "our" refer to Axonics, Inc. and our consolidated subsidiaries.

This Annual Report on Form 10-K includes our trademarks and trade names, including, without limitation, Axonics®, Axonics R20™, Axonics F15™ and Bulkamid®, which are our property and are protected under applicable intellectual property laws. This Annual Report on Form 10-K also includes trademarks and trade names that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this

Annual Report on Form 10-K appear without the ® and ™ symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Item 1. Business.

Overview

We are a global medical technology company that develops and commercializes innovative and minimally invasive products to treat adults with bladder and bowel dysfunction, including: (i) implantable SNM systems to treat urinary urge incontinence (UUI) and urinary urgency frequency (UUF), together referred to as overactive bladder (OAB), as well as fecal incontinence (FI), and non-obstructive urinary retention (UR); and (ii) a urethral bulking agent (Bulkamid) to treat female stress urinary incontinence (SUI).

On January 8, 2024, we entered into an Agreement and Plan of Merger (the Merger Agreement) with Boston Scientific Corporation, a Delaware corporation (Boston Scientific), and Sadie Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Boston Scientific (Merger Sub), providing for the merger of Merger Sub with and into the Company (the Merger), with the Company surviving the Merger as a wholly owned subsidiary of Boston Scientific. The consummation of the Merger is subject to certain closing conditions, including, among others, the approval of our stockholders of the adoption of the Merger Agreement, the expiration or termination of any waiting periods (and any extension thereof) applicable to the consummation of the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the HSR Act), and any agreement with a governmental authority not to consummate the Merger, and receipt of certain additional consents, approvals, non-disapprovals and other authorizations of certain other governmental bodies applicable to the Merger. If the Merger is consummated, at the effective time of the Merger (the Effective Time), each share of common stock, par value $0.0001 per share, of the Company issued and outstanding immediately prior to the Effective Time (each, a Share and collectively, the Shares), other than Shares (i) held in the treasury of the Company or owned by any direct or indirect wholly owned subsidiary of the Company, (ii) owned by Merger Sub, Boston Scientific or any direct or indirect wholly owned subsidiary of Boston Scientific or (iii) held by holders who are entitled to and have properly exercised and not waived, withdrawn, failed to perfect or otherwise lost their appraisal rights, will be automatically canceled and converted into the right to receive $71.00 in cash, without interest.

See the section titled “Risk Factors - Risks Related to Our Proposed Merger with Boston Scientific” included under Part I, Item 1A “Risk Factors” of this Annual Report on Form 10-K for more information regarding the risks associated with the Merger.

SNM Systems

Our newly developed recharge-free sacral neuromodulation (SNM) system, Axonics F15, received FDA approval in March 2022 and utilizes a primary cell battery with an expected life of 15 years at typical stimulation parameters and over 20 years at lower amplitude settings and offers broad magnetic resonance imaging (MRI) access with 1.5T and 3.0T scanners. The recharge-free implantable neurostimulator (INS) is approximately 10cc in volume, utilizes constant current stimulation, an easy-to-use, intuitive recharge-free patient remote control and other related accessories.

Our newly developed fourth-generation rechargeable SNM system, Axonics R20, is only 5cc in volume and is designed to last 20 or more years in the human body. R20 provides constant current stimulation and offers broad MRI access with 1.5T and 3.0T scanners. R20 utilizes an easy-to-use, intuitive patient remote control and requires recharging for only one hour every 6 to 10 months, which is the longest interval between recharging among available rechargeable SNM systems. The R20 received FDA approval in January 2023 and replaces the previous rechargeable SNM system offered by Axonics that was the first to be marketed worldwide.

We began U.S. commercialization in the middle of the fourth quarter of 2019 after receiving FDA premarket approval (PMA) of our first rechargeable SNM system. We also have marketing approvals from regulators in Europe, Canada, and Australia for certain SNM systems for most relevant clinical indications.

SNM therapy has been commercially available in the United States for over 25 years and has been clinically proven to provide a safe, effective, reversible, and long-lasting symptom relief. We believe that our SNM systems offer therapeutic benefits and advantages compared to our competitor’s SNM systems.

We engineered our SNM systems to deliver constant-current stimulation, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, which we believe provides a more consistent therapy over time and reduces management of the therapy. Our SNM systems include an easy-to-use wireless patient remote control that does not require recharging or replacement batteries. We also designed and custom built a clinician programmer that guides the implanting physician through lead placement and stimulation programming.

We focus most of our sales and marketing efforts in the United States where reimbursement for SNM therapy is well-established and covered by the vast majority of U.S. insurers and Medicare.

Urethral Bulking Agent

On February 25, 2021, we acquired Contura Limited (Contura) and its Bulkamid product, a urethral bulking hydrogel indicated for the treatment of female SUI.

SUI is a common condition that afflicts women of all ages, with childbirth as one of the main contributing factors. SUI is caused by weakness in the pelvic floor, preventing the urethra from closing fully when sudden pressure is put on the bladder. This can allow urine to leak out during normal daily activities such as coughing, laughing, exercising, or lifting an object.

Bulkamid received a Conformité Européenne (CE) Mark in 2003 and a PMA from the FDA in 2020 and is sold through a combination of a direct sales force in the United States, Germany, United Kingdom, and the Nordic countries and distributors in certain international markets.

As a next-generation bulking agent, we believe Bulkamid addresses the shortcomings of legacy particulate-based bulking agents. It is a unique and patented non-particulate hydrogel that is injected into the urethral wall to restore the natural closing pressure of the urethra. It is a simple, quick, and easy-to-learn and perform procedure that can be performed in either a physician's office or an outpatient facility.

Bulkamid is biocompatible, consisting of 97.5% water, and does not induce a chronic inflammatory response. Bulkamid's bulking effect is aided by the volume of each injection being predictable, controllable, and precise. Bulkamid retains its bulking characteristics for a number of years, thereby maintaining efficacy and providing women with long lasting relief of their SUI symptoms. Bulkamid is clinically validated and generates high rates of patient satisfaction.

Our Strategy

Our goal is to become a global leader in providing effective and long-term solutions to treat incontinence. To achieve this goal, we are pursuing the following strategies:

- ***Continue to promote awareness of our SNM systems among healthcare providers.*** We believe that of the approximately 45,000 physicians addressing OAB and FI in the United States, approximately 4,000 or less than 10% are actively performing SNM procedures. We intend to help physicians in their direct-to-patient outreach and are pursuing Axonics-sponsored direct-to-consumer marketing initiatives. We believe this will increase the number of patients seeking treatment and ultimately undergoing SNM procedures.
- ***Continue to develop a commercialization infrastructure with a dedicated direct sales team.*** We focus the significant majority of our sales and marketing efforts in the United States since we believe that approximately 90% of the annual global SNM sales are generated in this market. To achieve our commercialization goals, we plan to continue to provide our sales representatives and clinical specialists with sufficient resources to achieve success.
- ***Continuously innovate to introduce enhanced SNM product offerings.*** We continue to invest in research and development activities to expand our suite of products for SNM therapy. In January 2023, we received FDA approval for the Axonics R20, our fourth-generation rechargeable SNM system.
- ***Further penetrate our initial target market by promoting patient and practice awareness.*** Currently, we estimate that less than three percent of patients worldwide that could benefit from SNM therapy have been implanted with an SNM device. We believe that there are several factors that influence this low historical penetration of the potential market. First, even after patients were made aware of SNM therapy by a

physician, many patients elected not to undergo the procedure due to the limitations of the legacy product, such as the need for multiple INS replacement surgeries and the large device size. Second, we believe that a large number of adults with OAB and/or FI symptoms are unaware of SNM therapy. Third, we believe that more physicians should offer SNM to their patients. We intend to educate physicians that are unfamiliar with the benefits of SNM therapy and the attractiveness to patients of our SNM systems. We intend to increase physician and patient awareness through engagement, direct patient outreach, presentation of clinical data at medical conferences and publication of clinical data in peer reviewed journals.

- ***Expand our product offerings with complementary products in our market.*** We believe our acquisition of Bulkamid is highly synergistic and positions us to become a global leader in incontinence solutions. We have been able to leverage our existing commercial footprint of sales and clinical specialists in the United States and Europe who call on urogynecologists and urologists for SNM, the same type of physicians who treat SUI. We also believe that extending our urology platform to offer solutions for both OAB and SUI will enhance our value proposition and drive additional SNM sales.

Our Markets

The market for SNM therapy is large and growing. Our SNM target market consists of millions of adults in the United States and Europe with symptoms of UUI, UUF, FI, and UR who have progressed through the care pathway and are eligible to be treated with SNM therapy.

We believe that the U.S. SNM market is now approximately $850 million, representing approximately 55,000 annual patient implants. We believe the SNM market will continue to increase for the foreseeable future driven by increased awareness and education of SNM therapy, greater expectations for quality of life, and improved patient attitudes toward receiving medical attention. In addition, market growth is anticipated to accelerate due to continued innovation and the introduction of new efficacious and long-lived products for SNM therapy. We believe that this represents a compelling opportunity for our SNM systems to capture market share and grow the market for SNM therapy.

The market for SUI therapy is highly underpenetrated, with approximately 22 million women in the United States having moderate to severe SUI or mixed urinary incontinence (MUI) symptoms, which is urinary incontinence related to both stress and urgency. The first-line treatment options for SUI begin with lifestyle changes and continence pessaries. SUI lacks pharmacologic treatments, with patients next advancing to urethral bulking agents, pelvic floor sling surgery or colposuspension. We estimate that less than half of these women have sought medical treatment, most of whom were offered conservative therapy or opted for no treatment due to a lack of non-invasive treatment options with high efficacy.

While we anticipate expanding into other geographic regions over time, we are primarily focused on marketing our products in the United States and Europe due to the large overall market size.

Overview of Overactive Bladder

OAB causes a sudden urge to urinate that is difficult to stop and often leads to the involuntary leakage of urine. OAB typically presents via a combination of several symptoms, including abnormally frequent urination that is typically defined as urinating more than eight times per day, involuntary leakage of urine, or incontinence, and the disruption of sleep to wake up and pass urine, or nocturia. The combination and severity of OAB symptoms varies from person to person. UUF, when not accompanied by any other symptoms, does not include the involuntary leakage of urine. UUI is characterized by the sudden need to urinate accompanied by the involuntary loss of urine, regardless of frequency. Non-obstructive urinary retention or UR, which is the inability to empty the bladder, is not considered OAB.

A study published in 2022 by Patel, Ushma J. et al. found that approximately 19 million women in the United States have moderate to severe UUI or MUI symptoms. Study authors utilized publicly available data from the 2015-2018 National Health and Nutrition Examination Survey (NHANES). The NHANES is a major program of the National Center for Health Statistics, a part of the Centers for Disease Control and Prevention (CDC) and is designed to assess the health status of a nationally representative sample of the civilian, noninstitutionalized U.S. population. The study analyzed data from over 5,000 women that completed mobile examinations and computer-assisted personal interviews with standardized urinary incontinence questions.

We believe this survey is representative of the prevalence of OAB in the United States. Obesity and diabetes are frequent risk factors associated with OAB, and we believe that the increase in this high-risk population is one of the factors that has driven continued growth in the prevalence of OAB.

While historically many people with symptoms of OAB have gone undiagnosed, we believe this is beginning to change. We believe that improved access to care, decreased social acceptance of compromised quality of life, and longer life expectancy may all contribute to individuals being more proactive about acknowledging symptoms of OAB and seeking medical attention. Previously, patients have avoided discussing their symptoms with medical professionals because of misperceptions such as OAB symptoms being a normal and accepted consequence of aging, and lack of availability of treatments, misguided fear of the currently available treatments, and general availability of self-management tools, such as incontinence pads. In addition, we believe programs such as the Patient Quality Reporting System (PQRS), which was introduced by the Center for Medicaid and Medicare Services (CMS) in 2013, have helped to improve the frequency of dialogue around OAB between physicians and their Medicare patients as it includes incentives and penalties for primary care physicians based on various quality of care metrics, one of which addresses treating UUI symptoms.

The prevalence of OAB between women and men is generally similar, however, it varies by subtype. Women are more likely to suffer from UUI than UUF. In contrast, men are much more likely to suffer from UUF than UUI. Incidence by age also varies between men and women, as women often develop UUI at much younger ages than men. UUI symptoms in women are often associated with childbirth or menopause, while prostate enlargement, which is frequently associated with aging, is a leading cause of UUF symptoms in men. SNM is not indicated for treatment of UUF caused by prostate enlargement. These age and gender differences are significant because they may impact who seeks treatment for symptoms of OAB. Individuals with UUI are more likely to seek treatment due to the impact of incontinence on quality of life, and younger individuals are less likely to dismiss symptoms of OAB as an expected consequence of aging. As a result, women are more likely to seek treatment for symptoms of OAB than men.

Symptoms consistent with a diagnosis of OAB can develop due to a variety of underlying causes. When a patient consults a physician for the treatment of their symptoms related to OAB, the physician will first undertake a differential diagnosis in an attempt to determine the underlying cause of OAB.

If the physician is able to identify an underlying cause of OAB, the physician will then attempt to treat the underlying cause and alleviate the symptoms. When the physician is unable to identify an underlying cause of OAB symptoms, the patient is considered to have idiopathic OAB. We believe that these idiopathic patients are some of the best candidates for SNM therapy and where SNM therapy has been clinically proven to alleviate the symptoms associated with OAB.

OAB is associated with a significant economic burden to society. Direct medical and non-medical costs associated with OAB include the cost of diagnostics, pharmacological care, routine care, and OAB-related consequences such as urinary tract infections, skin infections, and depression. Further, indirect costs of OAB include caregiver wages and worker productivity losses resulting either from disability or absenteeism, as well as intangible costs including the quality-of-life impact and psychological burden. According to a study published in the American Journal of Managed Care in 2009, these OAB costs result in a total economic burden in the United States that is estimated to be between $24.9 billion and $36.5 billion.

Before treating patients with a third-line therapy such as SNM, physicians are required to prescribe first- and second-line therapies. As discussed further below, first-line therapies including behavioral changes such as diet and exercise, and second-line therapies include drug therapy. In the United States, in order to secure reimbursement, physicians are required to prescribe, and the patient must fail, or be contraindicated and/or refractory for, up to two second-line drug therapies before beginning SNM therapy, although the course of treatment and its duration may vary patient-by-patient based on physician judgment.

Current Treatments for OAB and Limitations

Patients with OAB follow a care pathway that transitions them, as necessary, through the progressive series of OAB treatment options. The care pathway directs physicians as to the progression of OAB treatments as follows:

- *First-line therapy*: behavioral changes, including conservative treatment options such as diet, exercise, timed voiding, pelvic floor exercises, and biofeedback;
- *Second-line therapy*: drug therapy, including two classes of OAB drugs, anti-muscarinics and beta-3 adrenergic agonists, with patients often trying multiple drugs; and
- *Third-line therapy*: minimally invasive therapy consisting of SNM, BOTOX injections and non-implantable Percutaneous Tibial Nerve Stimulation (PTNS).

First- and second-line therapies comprise the largest segment of the treatment market and are better known to physicians and hospitals than SNM therapy.

First-Line Therapies

First-line therapies represent conservative treatment options. Physicians may recommend that a patient make behavior modifications, such as drinking less fluid, training the bladder and/or pelvic muscles through Kegel exercises, among others. Such treatment options are limited in both duration and effectiveness.

Second-Line Therapies

Second-line therapies consist of medications, which comprise the largest segment of the OAB treatment market. Anticholinergics such as Oxybutynin, Vesicare, Detrol, Oxytrol, Enablex, and Sanctura are the most commonly prescribed medications. However, patients often do not fully comply with their drug prescriptions, due to perceived inefficacy and side effects. Mirabegron and Vibegron are the only available beta-3-adrenergic agonists that targets the bladder muscles and reduces bladder contractions to treat OAB. Physicians may also prescribe Tricyclic antidepressants such as Duloxetine and Imipramine, which are not FDA approved to treat the symptoms of OAB, but have been shown to relax the muscles in the bladder and reduce urgency.

Anti-muscarinic drugs inhibit the activation of muscarinic receptors on the bladder muscle by acetylcholine. Dry mouth is the most bothersome adverse event associated with antimuscarinic drugs and often a reason for treatment discontinuation. Side effects also include blurred vision, photophobia, tachycardia, difficulty in urination, hyperthermia, glaucoma, and mental confusion in the elderly.

Beta3-adrenergic agonists are relatively new drugs for OAB that work by relaxing the bladder muscle in the wall of the bladder by stimulating the beta-3 receptors that are found on the surface of the muscle cells. This relaxation of the bladder muscle helps to increase the capacity of the bladder to hold urine. In turn, this reduces the need to pass urine. The most common adverse events observed in clinical trials were hypertension, nasopharyngitis, and urinary tract infection.

Third-Line Therapies

Sacral Neuromodulation

Medtronic's InterStim I was approved by the FDA to treat the symptoms of UUI in 1997 and UUF in 1999. InterStim II was approved to treat the symptoms of OAB by the FDA in 2005, and to treat the symptoms of FI in 2011. Medtronic's InterStim Micro was approved by the FDA in 2020 and InterStim X was approved by the FDA in 2022. These systems have been implanted in hundreds of thousands of patients, with a majority of all implants having taken place in the United States.

BOTOX Injections

BOTOX injections into the bladder muscle were approved for treatment of symptoms of OAB by the FDA in 2013. BOTOX is injected through a cystoscopic procedure in a clinician's office or the outpatient surgery setting, and BOTOX treats OAB by blocking the signal from the bladder nerves to the bladder muscle. Key adverse events include recurrent urinary tract infections and self-catheterization due to inability to void. BOTOX injections are typically required every six to 12 months to maintain reduction of OAB symptoms. We believe the frequent need for injections and the adverse event profile are deterrents to initial and long-term preference for BOTOX injections, as

evidenced by an approximately 60% rate of cessation of BOTOX injections at three years, according to a retrospective study by Mohee et al. 2012.

Percutaneous Tibial Nerve Stimulation

PTNS involves in-office placement of an acupuncture needle in a patient's ankle to deliver electrical stimulation to the tibial nerve. Typically, patients undergo a 12-week trial period of weekly 60-minute PTNS sessions to evaluate whether the therapy provides significant symptom reduction. After this period, patients that continue with the therapy typically require monthly treatments to maintain symptom reduction. Adverse events of PTNS are minimal; however, lack of PTNS efficacy and lack of patient compliance result in PTNS generally providing less long-term effectiveness than SNM and BOTOX injection therapies.

Overview of Fecal Incontinence

FI is the inability to control bowel function, causing involuntary or accidental leakage from the rectum. Stimulation of the sacral nerves can reduce incontinence episodes, urgency, and frequency in people suffering from FI, and is an approved therapy for the treatment of FI in the United States and Europe. Moreover, a significant population of people suffering from FI also exhibit symptoms of OAB. SNM therapy can alleviate symptoms in patients suffering from either or both OAB and FI. Adults with FI that exhibit idiopathic symptoms or experience FI as result of obstetric or surgical injury or other prior trauma can be treated with SNM therapy.

People with FI experience even greater degrees of embarrassment and decreased quality of life than people with OAB. We believe shifting expectations and attitudes toward medical attention suggest this addressable market has the potential to expand.

A study published in 2014 by Ditah, Ivo et al. found that approximately 19 million adults in the United States exhibited symptoms of FI. Study authors utilized publicly available data from the 2005-2010 NHANES sample and based their analysis on over 14,000 adults that completed the FI section of the survey.

Symptoms consistent with a diagnosis of FI can develop due to a variety of underlying causes. When a patient consults a physician for the treatment of their symptoms related to FI, the physician will first undertake a differential diagnosis in an attempt to determine the underlying cause of FI. Underlying issues that can cause FI include obstetric injury, inflammatory diseases, prior surgeries, and other issues.

If the physician is able to determine that FI is caused by a clear, underlying disease, such as inflammatory bowel disease, the physician will then prescribe a care pathway to treat the underlying disease and alleviate the symptoms. Patients with FI caused by past trauma, mainly from obstetric damage, represent the majority of candidates for treatment of FI with SNM therapy. Additionally, in the absence of an identified underlying cause of FI symptoms, the patient is considered to have idiopathic FI.

Our SNM Systems

We believe that our proprietary SNM systems provide a minimally invasive, effective, and long-lasting solution for patients with bladder and bowel dysfunction. We have marketing approvals in the United States, Europe, Canada, and Australia for all relevant clinical indications.

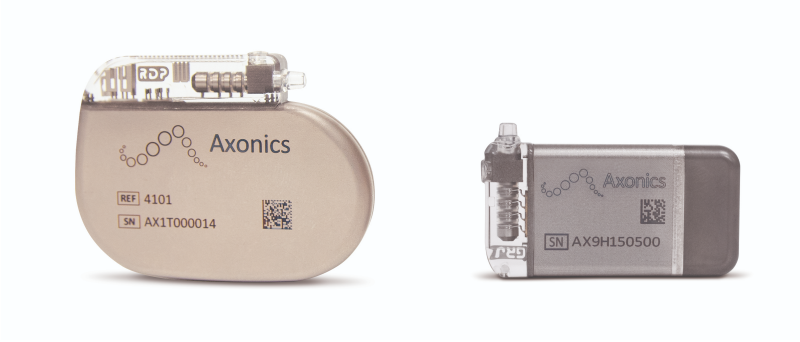
Our SNM systems include two implantable components and various external components.

Implantable Components for Patient

- Miniaturized INS, which houses the electronics for the device. The Axonics R20 is a fourth-generation rechargeable SNM system that utilizes an INS that is 5cc in volume and is intended to provide six to ten months of battery life between charges under normal use conditions. The Axonics F15 is a recharge-free SNM system that utilizes an INS that is 10cc in volume and powered by a primary cell battery.

- Tined four-electrode lead, which is implanted next to the targeted sacral nerve and delivers stimulation to the nerve. The tines help anchor the lead in its desired position.

Implantable Neurostimulators



F15 and R20

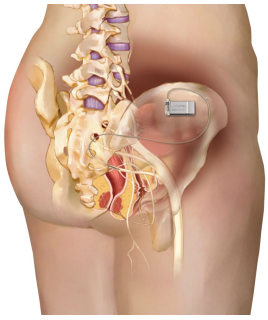
External Components for Patient

- Wireless charging device, which allows transcutaneous charging of the Axonics R20 INS. The charger uses an easy-to-understand combination of visual, audio and haptic indicators to provide information about the charging status. Further, it has the ability to be held into position by an adhesive fixation device or a reusable and flexible belt, which significantly enhances patient mobility.
- Wireless remote control that communicates with the device at a range of up to approximately three feet, which is a small and easy-to-use device that allows the patient to adjust stimulation intensity levels, modify program settings and turn stimulation on or off. The remote control includes a light-emitting diode light that indicates therapy intensity and the status of battery life of the INS.

Wireless Charging Device

Patient Remote Control

The implantable components of our SNM systems deliver mild electrical pulses to the targeted sacral nerve, most frequently the S3 nerve, in order to correct the dysfunction by restoring normal communication to and from the brain. The sacral nerves, including the S3 nerve, are located in the pelvic area and are responsible for controlling urethral sphincters, the bladder and anal sphincter muscles. The image below illustrates the location of the two implantable components of our INS and the four-electrode lead:



Benefits of our SNM Systems

We believe that our innovative and proprietary SNM systems offer several advantages compared to our legacy SNM systems. Our SNM systems offer the following important benefits:

- **Long-term solution**. Our devices are designed to last 15 to 20 or more years, compared to 7-10 years for the InterStim X of Medtronic plc (Medtronic).
- **Material benefits to physicians and payors.** We believe our SNM systems have the potential to enable physicians and facilities to utilize their resources more efficiently and significantly reduce overall costs to the healthcare system, due to the need for less replacement surgeries compared to InterStim.
- **Small and lightweight implantable neurostimulator.** Our rechargeable INS is approximately 60% smaller than InterStim X and our recharge-free INS is approximately 30% smaller than InterStim X.
- **Constant current.** Our SNM systems deliver constant-current stimulation, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body and we believe provides a more consistent and reliable therapy.
- **Improved patient experience.** Our SNM systems include a discrete, small and easy-to-use remote control.

- **Simplified therapy programming.** Our clinician programmer guides the provider through electrode stimulation programming and enables providers to access key data from the patient's INS.
- **Broad MRI conditions.** Our SNM systems allow for 1.5T and 3T full-body MRI scans under broad conditions.
- **Clinically proven results.** Two-year results from our clinical study show that 93% of patients achieved clinically significant improvements.

Overview of our External Trial System

Our external trial system (ETS) can be used during an evaluation period by a physician to determine if a patient is a good candidate for SNM therapy. This system includes a disposable external stimulation device, a disposable implantable lead, and a patient remote control. The external stimulation device is comprised of a temporary, non-rechargeable, current controlled pulse generator. The temporary implantable lead has a single electrode. In addition, our ETS can be used for a bilateral percutaneous nerve evaluation trial or a tined lead evaluation trial.

Overview of our Physician Tools

We provide physicians with a surgical tool kit to assist them while implanting our SNM systems. Our clinician programmer also allows physicians to connect to a patient's INS during the implant procedure and at other times to access key therapy data that is stored and maintained on the INS.

Clinician Programmer

We designed and custom built our touchscreen clinician programmer. The INS is programmed by and wirelessly communicates with the clinician programmer. This programmer is designed to simplify and assist physicians with electrode placement and stimulation programming. It has a series of touchscreens with a graphical user interface that provides information to the physician, such as measured data, test stimulation adjustments, and electrode configurations based on the utilization of proprietary algorithms. Further, it enables the clinician programmer to access any INS data and its complete history. The clinician programmer records and stores all data from the INS and enables a physician to store and retrieve this data electronically.

Clinician Programmer

Surgical Tool Kit

The single-use surgical tool kit provides the physician with the tools necessary for the SNM implant procedure.

Treatment with our SNM Systems

Patient Selection

SNM therapy is an approved therapy for patients with symptoms of bladder and bowel dysfunction. This therapy is not intended for patients with a mechanical obstruction such as benign prostatic hyperplasia, a tumor, or urethral stricture. Further, the therapy is not indicated for pregnant women or pediatric use.

SNM therapy for bowel dysfunction is indicated for patients who are not candidates for more conservative treatments.

Implantation

Before receiving an Axonics SNM system, a patient in the United States typically undergoes an external trial period.

External Trial Period

The short external trial procedure, which typically lasts approximately 30 minutes, is generally performed in the office or outpatient setting and typically involves a percutaneously placed lead, which a physician implants near the targeted sacral nerve using a needle, with the location confirmed utilizing fluoroscopy and intraoperative muscle responses evoked by test stimulation. The lead is then connected to a temporary, disposable external trial stimulator, which provides stimulation for the therapy. The trial period can last between a few days to several weeks after which the physician evaluates the effectiveness of SNM therapy through several measures, including bladder or bowel episodes and patient satisfaction. The vast majority of patients proceed from an external trial to permanent implant; the percentage of conversion is dependent on the quality of the implant procedure, external trial type and patient response to the stimulation.

Permanent Implant

Patients who have undergone a successful external trial period are eligible for a permanent INS implant procedure. The permanent implant procedure typically occurs in an ambulatory surgical center or hospital outpatient setting, usually lasting under an hour, and includes implantation of the INS and, if a temporary lead was used for the trial, implantation of the permanent lead. The INS is inserted through a small incision into a pocket in the subcutaneous fat of the upper buttocks, and the lead body is tunneled to the INS pocket and connected to the INS.

Activation and Programming

Immediately following the implant procedure or within a week thereafter, the patient has their stimulation settings programmed. Stimulation settings are adjusted to ensure they are comfortable to the patient. A reprogramming session may be necessary to achieve and maintain symptom reduction or to address discomfort. After initial programming, a patient has the ability to modify the therapy with the patient remote control.

Our Clinical Results and Studies with our SNM Systems

We have a body of compelling clinical evidence that demonstrates the safety, effectiveness, and sustained benefits of our SNM systems. We have two clinical studies relating to our rechargeable SNM system, a European study, RELAX-OAB, and a U.S. pivotal study, ARTISAN-SNM.

In June 2018, we completed the enrollment and implantation of 129 patients with UUI for our ARTISAN-SNM pivotal study. These patients were evaluated at 14 centers in the United States and five centers in Europe. All patients in our ARTISAN-SNM study reached the two-year post-implant follow-up by August 2020, resulting in completion of the ARTISAN-SNM study.

Key highlights of our ARTISAN-SNM pivotal study at two-years are as follows:

- 113 of the 121 implanted patients completing the two-year visit, or 93%, were therapy responders. Of the 129 patients initially treated, 88% were therapy responders at two years (113 out of 129);
- 93 of the 113 therapy responses, or 82%, had a ≥75% reduction in urgency incontinence episodes;
- 94% of patients reported being “satisfied” with the therapy; and

- No serious device-related adverse events have been reported.

Our European RELAX-OAB study began in June 2016 and evaluated 51 patients at seven sites in Europe with OAB subtypes UUI and/or UUF. All patients were evaluated to determine if they were therapy responders, which was defined as showing at least a 50% reduction in the number of average leaks or voids per day or a reduction to less than eight voids per day, in each case on a three-day bladder diary, at various times post-implant. We are following patients out to two years in this study and may follow patients out to five years at selected study sites.

Key highlights of our European RELAX-OAB study at two-years are as follows:

- Therapy responder rate for the 37 patients who continued with study follow-up was 90% for test responders and 76% for all implanted patients;
- 93% of test responders and 87% of all implanted patients were "satisfied" with the therapy provided by our rechargeable SNM system; and
- No serious device-related adverse events have been reported.

Our Bulkamid Product

Bulkamid is a urethral bulking agent in the form of a non-particulate hydrogel, consisting of 97.5% water and 2.5% polyacrylamide. Bulkamid is injected into the soft tissue of the urethra, adding volume to narrow the lumen of the urethra and to support the closing mechanism of the urethra, thus preventing urine leakage. Urethral bulking does not close the urethra totally; the urethra still opens normally to allow for urination.

Bulkamid achieves its bulking effect by the volume of the gel injected, unlike competitive bulking agents that achieve bulking effect through their micro particles and the body's inflammatory reaction to the particles.

The Bulkamid procedure is minimally invasive, with no cuts or incisions necessary, and typically takes less than 15 minutes. It is a simple procedure that is easy for physicians to learn and is usually performed in a physician's office or an outpatient facility, typically utilizing a local anesthetic. The injections are made into 3 to 4 locations in the urethral wall; the total volume injected is approximately 2 mL, equivalent to half a teaspoon. The patient is able to return home shortly following the procedure.

The majority of women treated with Bulkamid report dryness or improvement in their symptoms, with many seeing that improvement as soon as they leave the physician's office, hospital or clinic. Whilst experiencing no leakage at all is the most desired outcome of treatment, many women consider a successful treatment to be a meaningful decrease in the amount and frequency of urine leakage due to SUI such that they can go about their daily activities. If relief from symptoms is not sufficient, an additional injection of Bulkamid (a "top-up" injection) can be given to help achieve desired results.

In Bulkamid clinical studies, women were asked how effective their treatment was 12 months after their initial injection. Over three quarters of women reported that their incontinence was either cured or improved in one study, while in another study approximately two-thirds of women reported being dry. A Bulkamid clinical study has also shown that most of the women treated over 7 years ago still report a benefit.

Sales and Marketing

We are primarily focused on commercializing our products in the United States, which accounts for the vast majority of sales worldwide. We have established a significant commercial infrastructure, with approximately 210 sales representatives and managers and approximately 230 clinical and therapy support specialists in the United States. When making hiring decisions for these roles, we prioritize individuals with strong sales backgrounds who also have existing relationships with urologists and urogynecologists. We expect to focus the significant majority of our sales and marketing efforts in the United States where reimbursement for our therapies are well established and covered by the vast majority of U.S. insurers and Medicare.

Through our specialized and dedicated direct sales organization, we are targeting urologists, urogynecologists and colorectal surgeons, primarily those who have experience performing SNM procedures.

In order to support our direct sales team, our clinical staff is primarily responsible for attending SNM implant procedures and assisting the implanting physician with programming the device. Based on our experience to date, we believe that physicians require minimal training to start implanting our SNM systems.

We are promoting broader awareness of SNM and Bulkamid therapies for the treatment of OAB among patients and physicians, as well as awareness of the benefits and advantages of our products. We have expanded our awareness raising activities, including direct to consumer advertising on Facebook and national television ads, publication of scientific data in peer reviewed journals and education of physicians.

Although our main commercial priority is the United States, in November 2018, we launched a limited commercial effort in Europe. With the addition of the Bulkamid international sales force, we currently have approximately 20 dedicated sales representatives and clinical specialists in the United Kingdom, Germany, Netherlands, the Nordic countries, Canada, and Australia, with distributors serving certain other international markets around the world.

Third-Party Coverage and Reimbursement

In the United States, we derive revenue from the sale of our products to hospitals and ambulatory surgical centers, 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 SNM systems 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. Third-party payors require physicians and hospitals to identify the product and service for which they are seeking reimbursement by using Current Procedural Terminology (CPT) codes, which are created and maintained by the American Medical Association. As SNM therapy has been widely used in patients for over 20 years in the United States, reimbursement codes and payments are well-established and the procedure is covered by Medicare, Medicaid and private health insurance plans. Similarly, urethral bulking agent treatment reimbursement codes and payments are well-established and the procedure is covered by Medicare, Medicaid and private health insurance plans.

Physician reimbursement under Medicare is generally based on a defined fee schedule (the Physician Fee Schedule), through which payment amounts are determined by the relative value of the service rendered by the physician. Medicare generally provides reimbursement to hospitals and ambulatory surgical centers for SNM therapy under the hospital outpatient prospective payment system and the Ambulatory Surgical Center Payment System, respectively, which reimburse to the hospital or ambulatory surgical center, as applicable, a bundled amount generally intended to cover all facility costs related to procedures performed in the outpatient setting. The typical Medicare payment for facility and physician services for an SNM trial and full system implant ranges from approximately $22,000 to approximately $28,000, which covers the cost for the devices and the implantation procedures.

SNM procedures are eligible for payment under existing CPT code 64561 for percutaneous implantation of a lead near the sacral nerve and CPT code 64590 for insertion or replacement of a peripheral or gastric neurostimulator, which includes a neurostimulator for SNM therapy. Reimbursement rates vary based on several factors, including, but not limited to, the payor, geographic location, the procedure performed, contract terms, the facility in which the procedure is performed and other factors.

Most large insurers have established coverage policies in place to cover SNM therapy. Certain commercial payors have a patient-by-patient prior authorization process that must be followed before they will provide reimbursement for SNM therapy. These processes typically involve the treating physician submitting a form to the payor that provides information about the past treatments provided to the patient that proved ineffective and the physician’s recommendation that the patient be treated with SNM therapy. Although the prior authorization process can take several weeks, based on our industry knowledge, it generally results in positive coverage determination for these patients.

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 Europe. 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. Some countries or regions may require us to gather additional clinical data before granting coverage and reimbursement for our SNM systems.

Research and Development

We continue to invest in research and development activities to expand our suite of products for SNM therapy. Research and development expenses were approximately $34.9 million, $34.4 million, and $37.3 million for the years ended December 31, 2023, 2022, and 2021, respectively.

Manufacturing and Supply

We use a combination of in-house and outsourced vendors to manufacture various components of our products. Our contract manufacturers all have quality systems established that meet FDA requirements and are all recognized in their field for their competency to manufacture the respective portions of our SNM systems. We believe the manufacturers we currently utilize have sufficient capacity to meet our requirements and are able to scale up their capacity relatively quickly with limited capital investment. Certain components used in our products are supplied by single-source suppliers. Our suppliers manufacture the components they produce for us and test our components and devices to our specifications. We intend to maintain sufficient levels of inventory to enable us to continue our operations while we obtain another supplier in the event that one or more of our single-source suppliers were to encounter a delay in supply or end supply.

We employ a rigorous supplier assessment, qualification, and selection process targeted to suppliers that meet the requirements of the FDA and the International Organization for Standardization (ISO), and quality standards supported by internal policies and procedures. Our quality assurance process monitors and maintains supplier performance through qualification and periodic supplier reviews and audits. We are required to maintain ISO 13485 certification for medical devices sold in the European Economic Area (EEA), which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations.

We inspect, test, and assemble our products under strict manufacturing processes supported by internal policies and procedures. We perform our own final quality control testing of each product. However, 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.

Our suppliers are managed through our supplier management program that is focused on reducing supply chain risk. Key aspects of this program include managing component inventory at the supplier, contractual requirements for last time buy opportunities and second sourcing approaches for specific suppliers. Typically, our outside vendors produce the components to our specifications and in many instances to our designs. Our suppliers are audited periodically by our quality department to ensure conformity with the specifications, policies and procedures for our devices. In addition, we and our suppliers are subject to periodic unannounced inspections by U.S. and international regulatory authorities to ensure compliance with quality regulations. We believe that, if necessary, alternative sources of supply would be available in a relatively short period of time and on commercially reasonable terms.

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 of 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. We do not currently have arrangements in place for redundant supply of certain components of our products. If our current third-party manufacturers cannot perform as agreed, we may be required to replace those manufacturers or expand our in-house manufacturing, which could require significant capital investments. Although we believe that there are several potential alternative manufacturers who could manufacture these components, we may incur added costs and delays in identifying and qualifying any such replacement. We believe our manufacturing capacity is sufficient to meet global market demand for our products for the foreseeable future.

As previously discussed, and pursuant to the Manufacturing and Supply Agreement, Contura International manufactures all of the Bulkamid that we sell. We have rights to a technology transfer after June 30, 2022 that would enable us to insource the manufacturing of Bulkamid. Under the Manufacturing and Supply Agreement, Contura International is responsible for obtaining and maintaining all necessary permits, licenses, approvals and

authorizations required for the manufacture and sale of Bulkamid. The Manufacturing and Supply Agreement is subject to certain maximum purchase amounts of Bulkamid, which we believe are sufficient to meet the projected global demand for Bulkamid.

Competition

We believe our products offer several improvements for patients, physicians, and payors.

We consider our primary competition to be implantable SNM devices offered by Medtronic. Medtronic's InterStim X and InterStim Micro are currently the only other implantable SNM devices approved for commercial sale in the United States by the FDA. We also compete with other third-line treatments, 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 products or therapies designed to treat OAB, FI or SUI.

Intellectual Property

We rely on a combination of patent, copyright, trademark and trade secret laws, and confidentiality and invention assignment agreements, to protect our intellectual property rights.

We own numerous issued patents and pending patent applications that relate to our SNM systems and several issued patents and patent applications were licensed from AMF in 2013 pursuant to the License Agreement. As of December 31, 2023, we own 53 issued U.S. patents and 145 issued foreign patents, and 37 pending U.S. patent applications and 26 pending foreign patent applications. We also license from AMF 31 issued U.S. patents, as well as 53 issued foreign patents and two pending foreign patent applications. Issued patents owned or used by us will expire between 2023 and 2043.

In addition, we own or have rights to trademarks and domains in the United States and select locations internationally that we use in connection with the operation of our business.

We also rely upon trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with third party contract manufacturers, suppliers, employees, consultants and others who may have access to proprietary information that we own or license for use.

AMF License Agreement

On October 1, 2013, we entered into the License Agreement, pursuant to which AMF licensed us the AMF IP relating to AMF Licensed Products.

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products, or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) a minimum annual royalty (the Minimum Royalty), payable quarterly. The Minimum Royalty automatically increases each year, subject to a maximum amount of $200,000 per year. During the years ended December 31, 2023, 2022, and 2021, we have recorded royalties of $2.5 million, $3.3 million, and $6.3 million, respectively.

Government Regulation Applicable to Us

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, including the U.S. Department of Justice (DOJ), the Department of Health & Human Services - Office of the Inspector General (HHS-OIG), the United States Federal Communications Commission (FCC), the CMS, the Federal Trade Commission (FTC), as well as comparable authorities in the EEA, Australia, and Canada. These government authorities continue to highly scrutinize our industry. Our products are subject to regulation as a medical device under the Federal Food, Drug, and Cosmetic Act (FDCA), as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the EEA, Australia, and Canada governing clinical studies and the commercial sales and distribution of our products. We will be required to obtain authorization under appropriate regulatory authorities in countries outside the United States before commencing clinical studies and to obtain marketing authorization or approval before we can commercialize our product in those countries, whether or not we have or are required to obtain FDA clearance or approval for a product. The approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or PMA approval.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Devices for which there is no predicate device and which therefore are not eligible for 510(k) review, but project a low-to-moderate risk may be eligible for the de novo review process.

Our SNM systems are Class III devices and as such, we obtained PMA approval to market our devices for the treatment of OAB, FI and UR.

In a PMA, the manufacturer must demonstrate that the device is safe and effective. The PMA is typically supported by data from preclinical studies and human clinical studies. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with applicable portions of the Quality Systems Regulation (QSR).

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which may affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may require no clinical data or less extensive clinical data than the original PMA or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the change results in a device design so different from the original version that the data that were submitted with the original PMA are not applicable (i.e., not supportive) for the change in demonstrating a reasonable assurance of safety and effectiveness.

Post-market Regulation - United States

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment, registration and device listing with the FDA;

- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- the federal Physician Payments Sunshine Act and various state and foreign laws on reporting remunerative relationships with health care providers;
- the U.S. Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- the U.S. False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of a cleared device, or approval of a supplement for certain modifications to PMA devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, under which the FDA can order device recalls under certain circumstances and that require manufacturers report to the FDA voluntary field corrections and product recalls or removals if undertaken to reduce a risk to health or to remedy a violation of the FDCA that may present a risk to health;
- complying with the new federal law and regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products or any future product candidates;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;

- refusal to permit the export or import of our products or future product candidates; or
- criminal prosecution.

In addition, other U.S. federal and state government authorities, including but not limited to the DOJ, HHS-OIG, FCC and CMS, have broad enforcement powers and can impose various sanctions under the U.S. Anti-Kickback Statute, the U.S. False Claims Act, and various other laws. These sanctions could include but are not limited to fines, civil penalties, criminal prosecutions, and agreements such as Deferred Prosecution Agreements or Corporate Integrity Agreements, under which we may be required to establish additional controls to ensure compliance.

Regulation of Medical Devices in the EEA and the United Kingdom (U.K.)

Medical devices, other than active implantable medical devices (AIMDs), placed on the market in the EEA (which is comprised of the 27 Member States of the European Union (EU) plus Norway, Liechtenstein and Iceland) must comply with the essential requirements set out in Annex I of the Directive 93/42/EEC (Medical Devices Directive).

Separately, active implantable medical devices are governed by Directive 90/385/EEC, also known as the Active Implantable Medical Devices Directive (AIMD Directive). AIMDs are defined as medical devices that rely on a source of electrical energy or any source of power other than that generated by the body, which are totally or partially introduced, either surgically or medically, into the human body and intended to remain after the procedure. Our rechargeable SNM system, or our internal product, qualifies as an AIMD and must therefore comply with the AIMD Directive, more specifically with the essential requirements it sets out at Annex I.

An overarching essential requirement proscribed under both the AIMD Directive and the Medical Devices Directive is that any device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner.

In addition to the essential requirements set out under both the AIMD and Medical Devices Directives, the European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements, creating a rebuttable presumption that the device satisfies the essential requirements.

Under the AIMD Directive, manufacturers must demonstrate compliance with the essential requirements laid down in Annex I by undergoing a conformity assessment procedure. Conformity assessment procedures require 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.”

Similar requirements for conformity assessment procedures apply under the Medical Devices Directive, which vary according to the type of medical device and its classification. We believe that our external device is categorized as a Class IIa device under Annex IX of the Medical Devices Directive. As such, the conformity assessment procedure requirements for our external device are identical to those detailed above for our internal product under the AIMD Directive.

If satisfied that the AIMD or other medical device conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity (see above). The manufacturer may then apply the CE mark to the device, which allows the device to be

legally placed on and traded within the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the product.

In order to demonstrate safety and effectiveness for their AIMDs and other medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive and Annex 7 to the AIMD Directive, as well as standards (if any) which may be imposed by national authorities of EEA states in addition to those set out in Annex X to the Medical Devices Directive and Annex 7 to the AIMD Directive (the Directives). Clinical studies for medical devices usually require the approval of an ethics review board and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

The European Parliament adopted the Medical Devices Regulation (Regulation 2017/745), which is directly applicable in the EEA. This is intended to eliminate current differences in the regulation of medical devices among EEA countries. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

Starting January 1, 2021, all medical devices sold in the United Kingdom must meet new regulatory requirements due to the U.K.'s departure from the EU or "Brexit." Among other things, companies must register their devices with the U.K. Medicines & Healthcare Regulatory Agency (MHRA) and may need to change their product marking and labeling. In addition, if the company is not based in the United Kingdom, it must appoint a U.K. Responsible Person to register with the MHRA and assist the company in meeting U.K. regulatory requirements.

U.S. Fraud and Abuse and Physician Payment Transparency Laws

Various U.S. federal and state laws restrict our business practices regarding items of value provided to healthcare providers including, without limitation, the U.S. Anti-Kickback Statute, the U.S. False Claims Act, and the U.S. Physician Payments Sunshine Act.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including cash, in-kind items, meals, travel, lodging, consulting or research agreements, grants, donations, charitable contributions, free equipment or services, royalty arrangements, stock, stock options, and the compensation derived through ownership interests.

Recognizing that the U.S. Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the U.S. Department of Health and Human Services has established various "safe harbors," that if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn and interpreted narrowly. Government authorities may claim that our arrangements with physicians, hospitals and other persons or entities do not fully meet the stringent criteria specified in these safe harbors.

Violations of the U.S. Anti-Kickback Statute may result in civil monetary penalties and can also result in criminal penalties, including criminal fines and imprisonment. In addition, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. Government authorities may contend that we are liable under the U.S. Anti-Kickback Statute because of the intentions or actions of the parties with whom we do business, if we acted with deliberate ignorance or reckless disregard. The majority of states also have anti-kickback laws that establish similar prohibitions, and in some cases, may apply more broadly.

The U.S. False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act, if a person acts with deliberate ignorance or reckless disregard.

In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the U.S. False Claims Act in the name of the government and share in the proceeds of any recovery. A violation may result in penalties and provide the basis for exclusion from federal healthcare programs.

Additionally, the U.S. Physician Payments Sunshine Act requires annual reporting of transfers of value to certain healthcare providers by companies whose products are reimbursable under Medicare, Medicaid or other federal healthcare programs. A manufacturer's failure to submit timely, accurate and complete information under the Sunshine Act may result in civil monetary penalties. Certain U.S. states similarly require tracking and reporting of certain transfers of value to healthcare providers and some mandate implementation of commercial compliance programs or, impose restrictions on device manufacturer marketing practices.

Anti-Bribery and Corruption Laws

Our operations outside the United States are subject to the U.S. Foreign Corrupt Practices Act (FCPA). The FCPA generally prohibits companies and their intermediaries from engaging in bribery or making prohibited payments to foreign officials for the purpose of obtaining or retaining business or an official government action. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. We also are subject to similar anti-corruption or anti-bribery laws in Europe, Australia, and Canada, and would be subject to such laws in many other countries in which we might choose to do business.

FCC Regulation

Because our SNM systems include a wireless radio frequency transmitter and receiver, the devices are subject to equipment authorization requirements in the United States. The FCC requires advance clearance of all radio frequency devices before they can be imported into, sold or marketed in the United States. These clearances ensure that the proposed products comply with FCC radio frequency emission and power level standards and will not cause interference.

Data Privacy and Security Laws

We are also subject to various U.S. federal, state and foreign laws that protect the confidentiality and restrict the use and disclosure of personal information, such as patient health information.

For example, the U.S. Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), establishes uniform standards governing the use and disclosure of protected health information (PHI) and requires healthcare providers, called "covered entities", to maintain certain safeguards to protect the privacy and security of PHI. HIPAA also requires business associates (independent contractors or agents of covered entities that create, receive, maintain, or transmit PHI on behalf of a covered entity) to enter into business associate agreements with the covered entity. These agreements require the business associate to safeguard the covered entity's PHI against improper use and disclosure.

Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties, and, in certain circumstances, criminal penalties with fines and/or imprisonment.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits alleging negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance

audits of HIPAA covered entities and their business associates for compliance with the HIPAA privacy and security standards.

In the EU, we may be subject to various laws relating to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable individual). We may process personal data of our employees, our customers, and our vendors. These laws include the General Data Protection Regulation ((EU) 2016/679) (GDPR), the E-Privacy Directive 2002/58/EC and national laws supporting aspects of the GDPR and implementing the E-Privacy Directive. Each EU Member State has transposed the requirements laid down by the E-Privacy Directive into its own national data privacy regime, while the GDPR permits EU Member States to implement local legislation to supplement the GDPR, and therefore the laws may differ by jurisdiction, sometimes significantly. We need to ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws.

The GDPR is directly applicable in each EU Member State, resulting in a more uniform application of data privacy laws across the EU. Like the previous Directive, the GDPR requires that personal data may only be collected for specified, explicit and legitimate purposes based on legal bases for processing set out in the GDPR and local laws, and may only be processed in a manner consistent with those purposes. Personal data must be secure, not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection and must not be kept for longer than necessary for the purposes of collection. In addition, the GDPR also limits the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA. In particular, in order to process such data, explicit consent to the processing (including any transfer) is usually required from the data subject (being the person to whom the personal data relates).

The GDPR also imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR are significant—€20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher.

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.

Human Capital Resources

Workforce Overview

We take pride in our employees and the products and services we provide. We are committed to maintaining an environment that promotes job satisfaction, respect for fellow employees, personal responsibility, and integrity in all matters. We provide a welcoming, collaborative environment that nurtures talent and offers attractive health care and other employee benefits.

As of December 31, 2023, we had 797 employees. Of this total, 26 were employees based outside of the U.S. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our manufacturing, product development, warehouse and administrative employees are generally located in the same or adjacent facilities, which we believe contributes to our culture of strong manufacturing, engineering and customer service capabilities.

Inclusion, Diversity & Equity

We believe that a diverse workplace encourages creativity and a collaborative environment. We are committed to fostering an inclusive environment, treating all employees fairly, and providing equal opportunity. As of December 31, 2023, 34% of our U.S. workforce is ethnically diverse; women comprise 59% of our U.S. workforce; 47% of our manager and above employees are ethnically diverse; and 47% of our manager and above employees are women.

Workforce Compensation

Our compensation framework is designed to celebrate the value and contributions of our employees. We are committed to transparent communications on compensation. Our competitive approach to compensation reflects industry benchmarks and local market standards. Our programs include annual and long-term incentives that provide the means to share in the Company's success. To attract the best leaders, we offer competitive benefits and cash and equity incentives. We reward high-performing employees with an ownership stake in the company through restricted stock.

Pay Equity

Axonics provides competitive compensation by benchmarking with other leading medical device companies, using data to adjust salary ranges used to guide compensation decisions. We define pay as equal compensation for women, men, and all races/ethnicities who undertake the same work at the same level, experience, and performance.

Company Information

We were incorporated in the State of Delaware in March 2012 under the name "American Restorative Medicine, Inc." In August 2013, we changed our name to Axonics Modulation Technologies, Inc. and in March 2021, we changed our name to Axonics, Inc. Our principal executive offices are located at 26 Technology Drive, Irvine, California 92618 and our telephone number is 1-877-929-6642. Our website is www.axonics.com. The information contained on or that can be accessed through our website is not incorporated by reference into this Annual Report on Form 10-K.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports are accessible free of charge on our website at www.axonics.com as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC also maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

Item 1A. Risk Factors.

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.

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.

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.

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.

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 will continue to incur substantial transaction-related costs in connection with 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.

We and our directors and officers may be subject to lawsuits relating to the Merger.

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.

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.

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.

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 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 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 for the years ended December 31, 2023, 2022, and 2021, respectively. As of December 31, 2023, we had an accumulated deficit of $380.4 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 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. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations. 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.

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 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;
- 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 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 manufacturers at a time that is costly or inconvenient for us;
- manufacturer demands for significant cost increases;
- interruption of supply resulting from modifications to, or discontinuation of, a 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 manufacturers for key components;
- difficulty identifying and qualifying alternative 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 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 we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our 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, 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.

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 result in 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 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 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 our control. These suppliers' ability to perform their respective obligations under their agreements with us is dependent on their operational and financial health, which could be negatively impacted by several factors, including changes in the economic and political and legislative conditions.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

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";
- 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 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.

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.

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. Axonics strongly disagrees that it is required to pay royalties on the

F15 product and that AMF has the right to 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 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 invest in research and development activities focused on enhancements to our SNM systems.

Developing enhancements to our SNM systems can be expensive and time-consuming and 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 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 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 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, reputation, 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, successfully complete any such acquisitions on favorable terms or at all, or

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 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 essential to our operations. We 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 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 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. 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 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 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 depends on our ability to attract and retain senior management and other highly qualified personnel.

Our success 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. Conversely, if the value of 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 could be adversely impacted, which could adversely affect our business, results of operations and financial condition and/or require us to increase the amount we expend on 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.

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.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the 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.

Security breaches, cyber-attacks, loss of data or other disruptions or incidents could expose us to liability and affect our business and reputation.

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 our operations and business strategy. Some of this information could be 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 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.

Risks Related to Legal Matters and Government Regulation

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.

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, 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.

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 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.

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 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.

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. In addition, any effective termination or loss of rights (including exclusivity) under the License Agreement could materially and adversely affect our ability to 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.

Risks Related to Our Common Stock

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 the 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 the 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 the 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 the 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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

We have adopted the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF) and established policies and processes for assessing, identifying, and managing material cybersecurity risks based upon cybersecurity threats, vulnerabilities, likelihood, and impact, and have integrated these processes into our overall risk management systems and processes, which are overseen by our Chief Operating Officer and Chief Financial Officer. We routinely assess cybersecurity risks that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct annual assessments to identify cybersecurity risks based on known threats and vulnerabilities, as well as assessments after any material change in our business practices that may affect information systems exposed to such cybersecurity risks. These risk assessments include identification of reasonably foreseeable internal and external threats and vulnerabilities, the likelihood that such threats will occur, and the impact on our business that could result from such occurrences. We then evaluate the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we adjust existing and implement new controls responsive to changes in the risk environment and maintain those controls to mitigate and minimize identified risks. This process includes reasonably addressing any identified gaps in existing safeguards and regularly monitoring the effectiveness of our controls over time. Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with the Director of IT who reports to our Chief Operating Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our controls and train our employees on these controls, in collaboration with IT and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage consultants, or other third parties, in connection with our risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards. We require each third-party service provider to certify that it has the ability, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect the Company.

We face a number of cybersecurity risks in connection with our business. Although such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we have, from time to time, experienced threats to and breaches of our data and systems, including malware and computer virus attacks. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, “Risk Factors,” in this Annual Report on Form 10-K.

Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats and vulnerabilities. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function directly as a whole, as well as through the audit committee. Our audit committee is responsible for evaluating our cyber security program, cyber risk environment, and related risks and, with management, reporting findings and actions under our cyber security program and cyber risk environment to the full board of directors.

Our Chief Financial Officer, Chief Operating Officer and Director of IT have substantial relevant expertise in the life sciences industry and formal training in the areas of information security and cybersecurity risk management, and are primarily responsible to assess and manage our material risks from cybersecurity threats with assistance from third-party service providers.

Our Chief Financial Officer and Chief Operating Officer oversee our cybersecurity policies and processes, including those described in “Risk Management and Strategy” above. The cybersecurity risk management program includes tools and activities to identify, protect against, detect, respond to, and recover from current and emerging cybersecurity risks, and plans and strategies to address those risks and mitigate harm caused by cyber incidents.

Our Chief Financial Officer provides periodic briefings to the audit committee regarding the Company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. Our audit committee provides regular updates to the board of directors on such reports.

Item 2. Properties.

In August 2014, we entered into a five-year operating lease for approximately 12,215 square feet of office space in Irvine, California, beginning on November 1, 2014, and expiring on October 31, 2019. In June 2019, the lease was amended to extend the expiration date to October 31, 2020. In September 2020, the lease was amended to extend the expiration date to July 31, 2022. In December 2021, the lease was amended to extend the expiration date to January 31, 2028, and in April 2023, the lease was amended to reduce the expiration date to March 31, 2024.

In November 2017, we entered into a seven-year operating lease for approximately 25,548 square feet of office space in Irvine, California, beginning on August 1, 2018, and expiring on August 31, 2025. In June 2019, the lease was amended to extend the expiration date to October 31, 2027. In April 2023, the lease was amended to reduce the expiration date to December 31, 2024 and in September 2023, the lease was amended to extend the expiration date to July 1, 2025.

In June 2019, we entered into an eight-year operating lease for approximately 32,621 square feet of office space in Irvine, California, beginning on January 15, 2020 and expiring on January 31, 2028. In April 2023, the lease was amended to reduce the expiration date to March 31, 2024 and in September 2023, the lease was amended to extend the expiration date to December 31, 2024. We use these premises as our new principal executive offices and for general office space. We are utilizing our other currently-leased spaces to conduct the training of our sales team and for manufacturing purposes.

In August 2020, we entered into a 38-month operating lease for approximately 5,693 square feet of warehouse space in Irvine, California, beginning on October 15, 2020 and expiring on December 31, 2023. In April 2023, the lease was amended to extend the expiration date to December 31, 2024 and in September 2023, the lease was amended to extend the expiration date to July 1, 2025. We use these premises for general warehouse space.

In March 2022, we entered into an 18-month operating lease for approximately 3,276 square feet of warehouse space in Irvine, California, beginning on July 1, 2022 and expiring on December 31, 2023. In April 2023, the lease was amended to extend the expiration date to December 31, 2024 and in September 2023, the lease was amended to extend the expiration date to July 1, 2025. We use these premises for general warehouse space.

In April 2023, we entered into a 120-month operating lease for approximately 145,960 square feet of office and warehouse space in Irvine, California, beginning on April 1, 2024 and expiring on March 31, 2034. We have been given control of this leased property as of November 1, 2023 and will use these premises as our new principal executive offices and for general office, manufacturing, and warehousing space.

For additional information, see Note 4 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Item 3. Legal Proceedings.

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.

On September 18, 2023, we commenced an arbitration against AMF with Judicial Administration and Arbitration Services (JAMS) seeking, among other things, resolution that AMF's purported attempt to terminate the License Agreement, dated October 1, 2013, was ineffective, that we do not owe any royalties to AMF for our F15 product and that we were not required to pay royalties on our F15 product under the License Agreement. AMF responded to the arbitration demand and asserted multiple claims. On October 5, 2023, we and AMF entered into an interim agreement while the arbitration proceedings were pending. Pursuant to this interim agreement, we agreed to deposit into an escrow account an amount equal to 4% of the net revenues previously received for sales of our F15 product that are the subject of dispute, which we have determined is approximately $16 million from January 1, 2022 through December 31, 2023, with interest, and will continue to deposit the disputed 4% of net revenues of our F15 product, with interest, into the escrow account during the pendency of the arbitration proceedings. We have paid and, under this interim agreement, will continue to pay 4% royalties on rechargeable products. While the loss from this contingency is reasonably possible, the Company does not believe that such loss is probable. We believe that AMF's claims are without merit and intend to vigorously defend against those claims, however, there can be no assurance as to the outcome of the arbitration.

In addition to the matters described above, we are and may continue to be involved in claims, legal proceedings, and investigations arising out of our operations in the normal course of business.

For additional information, see Note 4 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market for Common Stock

Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol "AXNX" since October 31, 2018. Prior to that date, there was no public market for our common stock.

Holders of Record

At February 26, 2024, there were approximately 715 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid cash dividends on our common stock. Because we currently intend to retain all future earnings to finance future growth, we do not anticipate paying any cash dividends in the near future.

Unregistered Sales of Equity Securities

Except as previously disclosed in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, we had no sales of unregistered equity securities during the year ended December 31, 2023.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since October 31, 2018, which is the date our common stock first began trading on the Nasdaq Global Select Market, to two indices: the Standard & Poor's (S&P) 500 Stock Index and the S&P Healthcare Equipment Index. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

$100 investment in stock or index	October 31, 2018	December 31, 2018	December 31, 2019	December 31, 2020	December 31, 2021	December 31, 2022	December 31, 2023
Axonics, Inc. (AXNX)	$ 100.00	$ 100.87	$ 184.98	$ 326.37	$ 373.83	$ 417.42	$ 415.42
S&P 500 Index (GSPC)	$ 100.00	$ 92.44	$ 119.14	$ 137.63	$ 176.22	$ 141.59	$ 175.90
S&P 500 Health Care Equipment Index (SPSIHE)	$ 100.00	$ 90.96	$ 111.33	$ 147.89	$ 152.79	$ 116.82	$ 109.86

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Components of Our Results of Operations

Net Revenue

Net revenue during the years ended December 31, 2023, 2022, and 2021 are as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
SNM net revenue			
United States	$ 284,846	$ 216,861	$ 153,837
International markets	6,959	5,130	3,753
	$ 291,805	$ 221,991	$ 157,590
Bulkamid net revenue[1]			
United States	$ 59,036	$ 40,178	$ 12,660
International markets	15,538	11,533	10,040
	$ 74,574	$ 51,711	$ 22,700
Total net revenue	$ 366,379	$ 273,702	$ 180,290

(1) The acquisition of Bulkamid was completed on February 25, 2021. Reported revenue includes sales from February 26, 2021 onwards.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of costs of the components of our SNM systems, third-party contract labor costs, overhead costs, Bulkamid product costs, as well as distribution-related expenses such as logistics and shipping costs. The overhead costs include the cost of material procurement and operations supervision and management personnel. We expect overhead costs as a percentage of net revenue to decrease as our sales volume increases. Cost of goods sold also include other expenses such as scrap and inventory obsolescence. We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our net revenue grows. We expect gross margin to vary based on manufacturing costs, regional differences in pricing, and discounts negotiated by customers.

We calculate gross margin as gross profit divided by net revenue. We expect future gross margin will be affected by a variety of factors, including manufacturing costs, the average selling price of our products, the implementation of cost-reduction strategies, inventory obsolescence costs, which may occur when new generations of our SNM systems are introduced, and to a lesser extent, the sales mix between the United States and international markets as our average selling price in the United States is expected to be higher than in international markets and foreign currency exchange rates. Our gross margin may increase over the long term to the extent our production volumes increase and we receive discounts on the costs charged by our contract manufacturers, thereby reducing our per unit costs. Additionally, our gross margin may fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and Development Expenses

Research and development expenses consist primarily of employee compensation, including stock-based compensation, product development, including testing and engineering, royalty expense, and clinical studies to develop and support our SNM systems, including clinical study and registry management and monitoring, payments to clinical investigators, and data management. Other research and development expenses include consulting and advisory fees, royalty expense, travel expenses, and equipment-related expenses and other miscellaneous office and facilities expenses related to research and development programs. Research and development costs are expensed as incurred. We expect to continue incurring research and development expenses in the future as we develop new products and expand to new markets. We expect research and development expenses as a percentage of net revenue to vary over time depending on the level and timing of initiating new product development efforts and new clinical development activities.

The following table summarizes our research and development expenses by functional area for the years ended December 31, 2023, 2022, and 2021 (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Personnel related	$ 23,044	$ 17,946	$ 19,192
Clinical development	892	1,038	862
Contract R&D and manufacturing	7,313	11,009	9,960
Royalty expense	2,546	3,337	6,282
Other R&D expenses	1,091	1,080	1,001
Total R&D expenses	$ 34,886	$ 34,410	$ 37,297

General and Administrative Expenses

General and administrative expenses consist primarily of employee compensation, including stock-based compensation, and spending related to finance, information technology, human resource functions, consulting, legal, and professional service fees. Other general and administrative expenses include director and officer insurance premiums, investor relations costs, office-related expenses, facilities and equipment rentals, bad debt expense, travel expenses, and impairment expenses. We expect our general and administrative expenses will significantly increase in absolute dollars as we increase our headcount and expand administrative personnel to support our growth and operations. Additionally, we anticipate increased legal expenses associated with the Medtronic Litigation and the arbitration with AMF. We expect general and administrative expenses to decrease as a percentage of net revenue primarily as, and to the extent, our net revenue grows.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of employee compensation, including sales personnel commissions and stock-based compensation, direct-to-consumer advertising programs, trade shows, booth exhibition costs, and the related travel for these events. Other sales and marketing expenses include consulting and advisory fees. We expect sales and marketing expenses to continue to increase in absolute dollars as we continue to expand our commercial infrastructure to both drive and support our expected growth in net revenue. However, we expect sales and marketing expenses to decrease as a percentage of net revenue in the long term primarily as, and to the extent, our net revenue grows.

Amortization of Intangible Assets

Amortization of intangible assets consist primarily of amortization expense on patent license asset, manufacturing license asset, technology, and customer relationships intangible assets. We amortize finite lived intangible assets over the period of estimated benefit using the straight-line method.

Acquisition-Related Costs

Acquisition-related costs consist of due diligence expenses incurred related to the Merger Agreement with Boston Scientific and expenses and changes in contingent consideration related to the Contura acquisition.

Acquired In-Process Research & Development

Acquired in-process research & development consists of expenses incurred related to the Radian acquisition.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest, dividend and accretion income and realized gain (loss) earned on cash equivalents, short-term investments and restricted cash, gains and losses on foreign currency transactions, net of interest expense payable under the Loan and Security Agreement with Silicon Valley Bank and other debt arrangements.

Income Tax Expense (Benefit)

Income tax expense (benefit) primarily consists of current U.S. federal, state and foreign taxes offset by the deferred tax benefit associated with amortization of intangible assets and losses in certain foreign jurisdictions.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table shows our results of operations for the years ended December 31, 2023 and 2022 (in thousands, except percentages):

	Years Ended December 31,		Period to Period Change
	2023	2022	
Net revenue	$ 366,379	$ 273,702	$ 92,677
Cost of goods sold	91,825	76,037	15,788
Gross profit	274,554	197,665	76,889
Gross Margin	*74.9 %*	*72.2 %*	
Operating expenses			
Research and development	34,886	34,410	476
General and administrative	45,754	40,238	5,516
Sales and marketing	189,562	156,019	33,543
Amortization of intangible assets	9,064	9,383	(319)
Acquisition-related costs	5,898	22,561	(16,663)
Acquired in-process research & development	15,447	—	15,447
Total operating expenses	300,611	262,611	38,000
Loss from operations	(26,057)	(64,946)	38,889
Other income (expense)			
Interest and other income	16,690	5,133	11,557
Loss on disposal of property and equipment	(1)	(69)	68
Interest and other income (expense)	624	(2,434)	3,058
Other income, net	17,313	2,630	14,683
Loss before income tax benefit	(8,744)	(62,316)	53,572
Income tax benefit	(2,656)	(2,618)	(38)
Net loss	(6,088)	(59,698)	53,610
Foreign currency translation adjustment	9,280	(18,587)	27,867
Comprehensive income (loss)	$ 3,192	$ (78,285)	$ 81,477

Net Revenue

Net revenue was $366.4 million in fiscal year 2023, an increase of $92.7 million, or 33.9%, compared to $273.7 million in fiscal year 2022. Net revenue is primarily derived from the sale of our products to customers in the United States and certain international markets. The increase in net revenue is primarily due to increased sales of our products to new customers in the U.S. and increased sales to our existing customer base. Our expanded SNM product offering and the acquisition of the Bulkamid product in February 2021 have significantly contributed to our expansion of customers and more patients being treated by our existing customers.

Cost of Goods Sold and Gross Margin

We incurred $91.8 million of cost of goods sold in fiscal year 2023, compared to $76.0 million incurred in fiscal year 2022. Gross margin was 74.9% in fiscal year 2023, compared to 72.2% in fiscal year 2022. The increase in gross margin is primarily due to higher sales volumes and product mix.

Research and Development Expenses

Research and development expenses increased $0.5 million, or 1.4%, to $34.9 million in fiscal year 2023, compared to $34.4 million in fiscal year 2022. The increase in research and development expenses was primarily attributable to an increase of $5.1 million related to personnel costs including salaries, wages, sales personnel commissions, stock-based compensation and other employee-related benefits, partially offset by a decrease of $3.7 million in contract R&D and manufacturing costs and a decrease of $0.8 million in royalty expense due to lower net revenue derived from the AMF Licensed Products.

General and Administrative Expenses

General and administrative expenses increased $5.5 million, or 13.7%, to $45.8 million in fiscal year 2023, compared to $40.2 million in fiscal year 2022, primarily as a result of an increase of $5.9 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, partially offset by a decrease of $1.0 million in legal fees primarily related to the Medtronic Litigation and the arbitration with AMF.

Sales and Marketing Expenses

Sales and marketing expenses increased $33.5 million, or 21.5%, to $189.6 million in fiscal year 2023, compared to $156.0 million in fiscal year 2022. The increase in sales and marketing expenses was primarily attributable to an increase of $29.4 million related to personnel costs including salaries, wages, sales personnel commissions, stock-based compensation and other employee-related benefits primarily related to increased headcount and commissions from the increase in net revenue.

Amortization of Intangible Assets

Amortization of intangible assets was $9.1 million in fiscal year 2023, compared to $9.4 million in fiscal year 2022. Amortization of intangible assets consisted primarily of technology and customer relationships acquired related to the Contura acquisition.

Acquisition-Related Costs

Acquisition-related costs were $5.9 million in fiscal year 2023 related to the Merger Agreement and the change in fair value of contingent consideration. Acquisition-related costs were $22.6 million in fiscal year 2022 related to the change in fair value of contingent consideration.

Acquired In-Process Research & Development

Acquired in-process research & development was $15.4 million in fiscal year 2023, which related to the Radian acquisition. We recorded no acquired in-process research & development in fiscal year 2022.

Other Income, Net

Other income, net was $17.3 million in fiscal year 2023 consisting primarily of interest, dividend and accretion income earned on cash equivalents, short-term investments and restricted cash. Other income, net was $2.6 million in fiscal year 2022, consisting primarily of interest and other income earned on cash equivalents and short-term investments, partially offset by losses on foreign currency transactions.

Income Tax Benefit

Income tax benefit was $2.7 million in fiscal year 2023 primarily related to current U.S., state and foreign taxes offset by a deferred tax benefit associated with amortization of intangible assets in certain foreign jurisdictions. Income tax benefit was $2.6 million in fiscal year 2022 primarily related to losses in certain foreign jurisdictions.

Comparison of the Years Ended December 31, 2022 and 2021

For a comparison of our results of operations and cash flows for the years ended December 31, 2022 and 2021, see “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our annual report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 1, 2023.

Liquidity and Capital Resources

We only began full-scale commercialization of our first rechargeable SNM system in late 2019. We have expended significant resources on research and development activities, growing our operations organization and building and training our sales organization, and sales and marketing activities to commercialize and market our line of SNM systems in the United States. We expect to continue to spend a significant amount of our existing resources on sales and marketing activities as we continue to commercialize and market our products in the United States and internationally.

We incurred net losses of $6.1 million, $59.7 million, and $80.1 million for the years ended December 31, 2023, 2022, and 2021, respectively, and had an accumulated deficit of $380.4 million as of December 31, 2023 compared to $374.3 million at December 31, 2022.

As of December 31, 2023, we had cash, cash equivalents, short-term investments and restricted cash of $357.7 million compared to $357.2 million at December 31, 2022. We expect that our cash, cash equivalents, short-term investments and restricted cash on hand will be sufficient to fund our operations through at least the next 12 months. We fund our operations through a combination of proceeds from public offerings of our common stock and cash receipts from sales of our products. As of December 31, 2023, we had no outstanding borrowings.

The following table sets out, as of December 31, 2023, our contractual obligations due by period (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations[1]	$ 44,267	$ 2,296	$ 8,399	$ 8,442	$ 25,130
Purchase Obligations[2]	21,445	21,445	—	—	—
Other Long-Term Liabilities[3]	2,000	200	400	400	1,000
Total	$ 67,712	$ 23,941	$ 8,799	$ 8,842	$ 26,130

(1) Our principal office is currently located at 26 Technology Drive, Irvine, California 92618, where we lease approximately 25,548 square feet of office space under a lease that terminates on July 1, 2025. In addition, we maintain offices at 15326 Alton Parkway, Irvine, California 92618, where we lease approximately 32,621 square feet of office space under a lease that terminates on December 31, 2024, and at 7575 Irvine Center Drive, Suite 200, Irvine, California 92618, where we lease approximately 12,215 square feet of space, and where we conduct the training of our sales team, under a lease that terminates on March 31, 2024. In April 2023, we entered into a 120-month operating lease for approximately 145,960 square feet of office and warehouse space in Irvine, California, beginning on April 1, 2024 and expiring on March 31, 2034 and will use these premises as our new principal executive offices and for general office, manufacturing, and warehousing space.

(2) Purchase obligations represent open purchase orders primarily for component materials and third-party contract labor costs at the end of the fiscal year. These purchase orders can be impacted by various factors, including the timing of issuing orders, the timing of the shipment of orders, and currency fluctuations.

(3) Represents the Minimum Royalty due under the License Agreement, and does not include royalty calculated as 4% of all net revenue derived from the AMF Licensed Products.

From time to time we enter into certain types of contracts that contingently require us to indemnify parties against third-party claims, including the License Agreement, and certain real estate leases, supply purchase agreements, and agreements with directors and officers. The terms of such obligations vary by contract, and in most instances, a maximum dollar amount is not explicitly stated therein. Generally, amounts under these contracts cannot be reasonably estimated until a specific claim is asserted, thus no liabilities have been recorded for these obligations on our balance sheets for any of the periods presented.

Beyond the next 12 months, our cash requirements will depend primarily on the amount of continued cash receipts from sales of our products, as well as our ability to develop or acquire new products, enter new markets, and

compete effectively. We cannot accurately predict our long-term cash requirements at this time. We may need to raise additional financing in the future to facilitate our business operations. If we raise additional funds by issuing equity securities, our stockholders could experience dilution. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain additional financing when needed to satisfy our liquidity requirements, we may be required to scale back our operations.

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Cash Flows

The following table presents a summary of our cash flow for the periods indicated (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Net cash provided by (used in)			
Operating activities	$ (2,016)	$ 3,191	$ (47,306)
Investing activities	(116,904)	(120,354)	(143,002)
Financing activities	(3,380)	133,968	170,513
Effect of exchange rate changes on cash, cash equivalents and restricted cash	979	1,163	(508)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (121,321)	$ 17,968	$ (20,303)

Net cash (used in) provided by operating activities

Net cash used in operating activities was $2.0 million in fiscal year 2023 and consisted primarily of a decrease from changes in net operating assets of $66.1 million and a net loss of $6.1 million, partially offset by non-cash charges of $70.2 million. Net operating assets consisted primarily of inventory and accounts receivable due to the commercial growth in the United States. Non-cash charges consisted primarily of stock-based compensation and acquired in-process research & development.

Net cash provided by operating activities was $3.2 million in fiscal year 2022 and consisted primarily of non-cash charges of $65.8 million, partially offset by a net loss of $59.7 million and a decrease from changes in net operating assets of $2.9 million. Net operating assets consisted primarily of inventory and accounts receivable due to the commercial growth of our SNM systems in the United States and the addition of Bulkamid sales. Non-cash charges consisted primarily of stock-based compensation and change in fair value of contingent consideration.

Net cash used in operating activities was $47.3 million in fiscal year 2021 and consisted primarily of a net loss of $80.1 million, a decrease from changes in net operating assets of $9.8 million, partially offset by non-cash charges of $42.6 million. Net operating assets consisted primarily of inventory and accounts receivable due to the commercial growth of our rechargeable SNM system in the United States and the addition of Bulkamid sales. Non-cash charges consisted primarily of stock-based compensation and depreciation and amortization.

Net cash used in investing activities

Net cash used in investing activities was $116.9 million in fiscal year 2023 and consisted of purchases of short-term investments, partially offset by sales and maturities of short-term investments.

Net cash used in investing activities was $120.4 million in fiscal year 2022 and consisted of purchases of short-term investments, partially offset by sales and maturities of short-term investments.

Net cash used in investing activities was $143.0 million in fiscal year 2021 and consisted primarily of the $140.7 million paid for the acquisition of Contura.

Net cash (used in) provided by financing activities

Net cash used in financing activities was $3.4 million in fiscal year 2023 and consisted primarily of payment of contingent consideration recognized at acquisition, partially offset by proceeds from exercise of stock options.

Net cash provided by financing activities was $134.0 million in fiscal year 2022 and consisted primarily of $128.3 million in net proceeds received in the August 2022 follow-on offering and proceeds from exercise of stock options.

Net cash provided by financing activities was $170.5 million in fiscal year 2021 and consisted primarily of $190.0 million in net proceeds received in the May 2021 follow-on offering, partially offset by a net debt repayment of $26.1 million.

Indebtedness

In June 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to the term loan under the Loan and Security Agreement with Silicon Valley Bank entered into in February 2021 were paid in full. The unamortized debt issuance costs of $4.4 million were expensed and recognized as interest expense.

In January 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to the Term Loan were paid in full. The unamortized debt issuance costs of $0.4 million were expensed and recognized as interest expense.

We have no current indebtedness arrangements.

For additional information regarding our Loan and Security Agreement and Term Loan, see Note 5 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Critical Accounting Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires our management to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates, and such differences may be material to our consolidated financial statements. The Company did not have any critical accounting estimates.

Recent Accounting Pronouncements

For recent accounting pronouncements, see Note 1 to our consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risk, foreign currency exchange rate risk and inflation risk as follows:

Interest Rate Risk

We had cash, cash equivalents, short-term investments and restricted cash of $357.7 million as of December 31, 2023, which came from public offerings of our common stock and cash receipts from our product sales. The goals of our investment policy are liquidity and capital preservation and we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash, cash equivalents, and short-term investments. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Foreign Currency Exchange Rate Risk

As we expand internationally our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. All of our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables would not have been material for the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

Inflation Risk

Inflationary factors, such as increases in our cost of goods sold and operating expenses, may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin and operating expenses as a percentage of our revenue if the selling prices of our products do not increase as much as or more than these increased costs.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Axonics, Inc.
Irvine, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Axonics, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated February 28, 2024 expressed an adverse opinion thereon.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (i) relates to accounts or disclosures that are material to the consolidated financial statements, and (ii) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Effect of material weakness in internal control over financial reporting related to information technology general controls

As disclosed in management's report on internal control over financial reporting, the Company identified a material weakness as of December 31, 2023 associated with not maintaining effective information technology general controls ("ITGCs") specifically in the area of user access including provisioning, user access reviews and restricted access. This could lead to downstream segregation of duties issues related to certain information technology ("IT") systems that support the Company's financial reporting process and manual controls impacting substantially all financial statement areas as well as the financial close and reporting process and preparation of financial statements and related disclosures that are dependent upon the IT systems.

Evaluating sufficiency of audit procedures over the significant financial statement accounts affected by the ITGC material weakness was determined to be a critical audit matter, because significant auditor judgment and effort that was required to design and execute the incremental audit procedures related to the significant financial statement accounts that are reliant on IT systems impacted by the ineffective ITGCs and to assess the sufficiency of the audit procedures performed and evidence obtained.

The primary procedures we performed to address this critical audit matter included:

- Utilizing our IT professionals to determine the timing, nature and extent of incremental procedures to be performed over significant financial statement accounts that are reliant on IT systems impacted by the ineffective ITGCs, including the impacted manual business process controls.
- Performing incremental procedures including, among others, (i) increasing sample selections compared to what we would have otherwise made to test completeness and accuracy of information produced by the Company, (ii) increasing sample selections compared to what we would have otherwise made to test certain significant financial statement accounts, and (iii) expanding nature and extent of journal entry testing.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2018.

Costa Mesa, California
February 28, 2024

Axonics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2023	2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 104,811	$ 238,846
Short-term investments	240,149	118,365
Accounts receivable, net of allowance for credit losses of $442 and $321 at December 31, 2023 and 2022, respectively	57,243	44,817
Inventory, net	79,940	55,765
Prepaid expenses and other current assets	9,279	7,282
Total current assets	491,422	465,075
Restricted cash	12,714	—
Property and equipment, net	10,760	6,798
Intangible assets, net	81,375	86,253
Other assets	24,235	6,813
Goodwill	99,417	94,414
Total assets	$ 719,923	$ 659,353
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 18,452	$ 9,070
Accrued liabilities	10,527	6,520
Accrued compensation and benefits	15,060	15,495
Operating lease liabilities, current portion	1,777	1,562
Other current liabilities	—	32,600
Total current liabilities	45,816	65,247
Operating lease liabilities, net of current portion	25,840	7,555
Deferred tax liabilities, net	10,703	16,412
Total liabilities	82,359	89,214
Commitments and contingencies (Note 4)		
Stockholders' equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, par value $0.0001 per share, 75,000,000 shares authorized at December 31, 2023 and 2022; 50,770,520 and 49,546,727 shares issued and outstanding at December 31, 2023 and 2022, respectively	5	5
Additional paid-in capital	1,033,778	969,545
Accumulated deficit	(380,352)	(374,264)
Accumulated other comprehensive loss	(15,867)	(25,147)
Total stockholders' equity	637,564	570,139
Total liabilities and stockholders' equity	$ 719,923	$ 659,353

See accompanying notes to consolidated financial statements.

Axonics, Inc.
Consolidated Statements of Comprehensive Income (Loss)
(in thousands, except share and per share data)

	Years Ended December 31,		
	2023	**2022**	**2021**
Net revenue	$ 366,379	$ 273,702	$ 180,290
Cost of goods sold	91,825	76,037	64,572
Gross profit	274,554	197,665	115,718
Operating expenses			
Research and development	34,886	34,410	37,297
General and administrative	45,754	40,238	30,041
Sales and marketing	189,562	156,019	105,789
Amortization of intangible assets	9,064	9,383	7,241
Acquisition-related costs	5,898	22,561	7,158
Acquired in-process research & development	15,447	—	—
Total operating expenses	300,611	262,611	187,526
Loss from operations	(26,057)	(64,946)	(71,808)
Other income (expense)			
Interest and other income	16,690	5,133	40
Loss on disposal of property and equipment	(1)	(69)	(91)
Interest and other income (expense)	624	(2,434)	(7,426)
Other income (expense), net	17,313	2,630	(7,477)
Loss before income tax (benefit) expense	(8,744)	(62,316)	(79,285)
Income tax (benefit) expense	(2,656)	(2,618)	782
Net loss	(6,088)	(59,698)	(80,067)
Foreign currency translation adjustment	9,280	(18,587)	(6,129)
Comprehensive income (loss)	$ 3,192	$ (78,285)	$ (86,196)
Net loss per share, basic and diluted (see Note 1)	$ (0.12)	$ (1.28)	$ (1.86)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	49,081,470	46,684,478	43,072,298

See accompanying notes to consolidated financial statements.

Axonics, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share and per share data)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance at December 31, 2020	39,931,030	$ 4	$ 522,296	$ (234,499)	$ (431)	$ 287,370
Issuance of common stock for employee stock option exercises for cash	522,495	—	6,757	—	—	6,757
Restricted Shares Award (RSA) issuances and forfeitures for terminations, net and stock-based compensation	520,411	—	17,793	—	—	17,793
Issuance of common stock for vesting of Restricted Stock Units (RSU) and stock-based compensation	169,054	—	7,371	—	—	7,371
Follow-on offering - issuance of 4,025,000 shares at $50.00 per share, less offering costs of $11,272	4,025,000	1	189,977	—	—	189,978
Issuance of common stock for acquisition of Contura Limited	1,096,583	—	55,728	—	—	55,728
Issuance of common stock for exclusive license asset	65,594	—	3,637	—	—	3,637
Foreign currency translation adjustment	—	—	—	—	(6,129)	(6,129)
Net loss	—	—	—	(80,067)	—	(80,067)
Balance at December 31, 2021	46,330,167	5	803,559	(314,566)	(6,560)	482,438
Issuance of common stock for employee stock option exercises for cash	364,352	—	5,662	—	—	5,662
RSA issuances and forfeitures for terminations, net and stock-based compensation	570,778	—	26,218	—	—	26,218
Issuance of common stock for vesting of RSU and stock-based compensation	268,930	—	5,800	—	—	5,800
Follow-on offering - issuance of 2,012,500 shares at $63.85 per share, less offering costs of $192	2,012,500	—	128,306	—	—	128,306
Foreign currency translation adjustment	—	—	—	—	(18,587)	(18,587)
Net loss	—	—	—	(59,698)	—	(59,698)
Balance at December 31, 2022	49,546,727	5	969,545	(374,264)	(25,147)	570,139
Issuance of common stock for employee stock option exercises for cash	219,763	—	4,250	—	—	4,250
RSA issuances and forfeitures for terminations, net and stock-based compensation	523,279	—	31,750	—	—	31,750
Issuance of common stock for vesting of RSU and stock-based compensation	215,968	—	12,786	—	—	12,786
Issuance of common stock for acquisition of in-process research & development	264,783	—	15,447	—	—	15,447
Foreign currency translation adjustment	—	—	—	—	9,280	9,280
Net loss	—	—	—	(6,088)	—	(6,088)
Balance at December 31, 2023	50,770,520	$ 5	$ 1,033,778	$ (380,352)	$ (15,867)	$ 637,564

See accompanying notes to consolidated financial statements.

Axonics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2023	**2022**	**2021**
Cash Flows from Operating Activities			
Net loss	$ (6,088)	$ (59,698)	$ (80,067)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Depreciation and amortization	12,487	11,721	9,126
Loss on disposal of property and equipment	1	69	91
Stock-based compensation	44,536	32,018	25,164
Acquired in-process research and development	15,447	—	—
Amortization of debt issuance costs	—	—	4,991
(Reversal of) provision for allowance of credit losses	121	(34)	(122)
Change in fair value of contingent consideration	2,400	22,230	2,740
Deferred income taxes	(6,569)	(859)	460
Other items, net	1,755	675	122
Changes in operating assets and liabilities, net of business acquisition			
Accounts receivable	(12,431)	(15,968)	(8,998)
Inventory	(25,753)	8,423	(1,108)
Prepaid expenses and other current assets	(10,403)	(862)	(940)
Other assets	(2,633)	(207)	(225)
Accounts payable	9,014	1,468	(2,862)
Accrued liabilities	3,887	1,032	(1,976)
Accrued compensation and benefits	(444)	3,112	6,155
Operating lease liabilities	27	71	143
Payment of contingent consideration	(27,370)	—	—
Net cash (used in) provided by operating activities	(2,016)	3,191	(47,306)
Cash Flows from Investing Activities			
Purchases of property and equipment	(3,550)	(2,223)	(2,261)
Acquisition of a business, net of cash acquired	—	—	(140,741)
Purchases of short-term investments	(426,604)	(175,110)	—
Proceeds from sales and maturities of short-term investments	313,250	56,979	—
Net cash used in investing activities	(116,904)	(120,354)	(143,002)
Cash Flows from Financing Activities			
Proceeds from exercise of stock options	4,250	5,662	6,757
Payment of contingent consideration	(7,630)	—	—
Payment of debt issuance costs	—	—	(106)
Proceeds from debt	—	—	75,000
Repayment of debt	—	—	(101,116)
Proceeds from offering of common stock upon follow-on public offering	—	128,498	201,250
Payment of common stock offering costs upon follow-on public offering	—	(192)	(11,272)
Net cash (used in) provided by financing activities	(3,380)	133,968	170,513
Effect of exchange rate changes on cash, cash equivalents and restricted cash	979	1,163	(508)
Net (decrease) increase in cash, cash equivalents and restricted cash	(121,321)	17,968	(20,303)
Cash and cash equivalents, beginning of year	238,846	220,878	241,181
Cash, cash equivalents and restricted cash, end of year	$ 117,525	$ 238,846	$ 220,878
Supplemental Disclosure of Cash Flow Information			
Cash paid for interest	$ 69	$ 1	$ 2,178
Cash paid for taxes	$ 255	$ 667	$ 1
Noncash Investing and Financing Activities			
Property and equipment acquired but not yet paid	$ 203	$ 67	$ —
Property and equipment acquired from tenant improvement allowance	$ 3,633	$ —	$ —
Common stock issuance for acquired in-process research & development	$ 15,447	$ —	$ —
Common stock issuance for business acquisition	$ —	$ —	$ 55,728
Contingent consideration for business acquisition	$ —	$ —	$ 7,630
Common stock issuance for exclusive license asset	$ —	$ —	$ 3,637
Accrued loan fees as debt issuance costs	$ —	$ —	$ 4,500

See accompanying notes to consolidated financial statements.

Note 1. Nature of Operations and Summary of Significant Accounting Policies

Nature of Operations

Axonics, Inc. (the Company) was incorporated in the State of Delaware on March 2, 2012 under the name American Restorative Medicine, Inc. The Company had no operations until October 1, 2013, when the license agreement between Alfred E. Mann Foundation for Scientific Research (AMF) and the Company (the License Agreement) was entered into. In August 2013, the Company changed its name to Axonics Modulation Technologies, Inc. In March 2021, the Company changed its name to Axonics, Inc.

The Company is a medical technology company that develops and commercializes innovative and minimally invasive products to treat bladder and bowel dysfunction. The Company has designed and developed both rechargeable (R20) and recharge-free (F15) implantable sacral neuromodulation (SNM) systems, which deliver mild electrical pulses to the targeted sacral nerve in order to restore normal communication to and from the brain to reduce the symptoms of overactive bladder (OAB), urinary retention (UR) and fecal incontinence (FI). The Company's products are protected by intellectual property based on Company-generated innovations and patents and other intellectual property licensed from AMF. The Company has regulatory marketing approvals in the United States for all relevant clinical indications. In Europe, Canada, and Australia, the Company has regulatory marketing approvals for most relevant clinical indications. The premarket approval (PMA) application for the Company's first rechargeable SNM system for the treatment of FI was approved by the U.S. Food and Drug Administration (FDA) on September 6, 2019, and the PMA application for the first rechargeable SNM system for the treatment of OAB and UR was approved by the FDA on November 13, 2019. Accordingly, the Company began U.S. commercialization of its first rechargeable SNM system in the fourth quarter of 2019.

Beginning in February 2021 with the acquisition of Contura Limited, the Company also markets Bulkamid, a urethral bulking agent to treat female stress urinary incontinence (SUI). Beginning in March 2022 with the FDA approval of the Company's long-lived, recharge-free F15 SNM implantable stimulator, the Company now markets and sells the F15 recharge-free system to customers in the United States in addition to the rechargeable SNM system. The new recharge-free SNM system and Bulkamid are protected by intellectual property based on Company-generated innovations or patents acquired as part of the Contura acquisition. For more information, see Note 9.

May 2021 Follow-On Offering

On May 14, 2021, the Company completed a follow-on offering by issuing 4,025,000 shares of common stock, at an offering price of $50.00 per share, inclusive of 525,000 shares of the Company's common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The net proceeds to the Company were approximately $190.0 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company.

August 2022 Follow-On Offering

On August 5, 2022, the Company completed a follow-on offering by issuing 2,012,500 shares of common stock, at an offering price of $63.85 per share, inclusive of 262,500 shares of the Company's common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The net proceeds to the Company were approximately $128.3 million, after deducting offering expenses payable by the Company.

Acquisition of in-process research & development (IPR&D) from Radian, LLC

In April 2023, the Company acquired the assets of Radian, LLC, for total consideration of the issuance of 264,783 shares of the Company's common stock and a potential future milestone payment of up to $2.5 million (the Radian acquisition).

The Company evaluated this acquisition in accordance with Accounting Standards Codification (ASC) 805, Business Combinations, to determine whether the asset acquired met the definition of a business. Included in the IPR&D is the historical know-how, software, formula protocols, designs, and procedures expected to be needed to complete the technology asset and receive regulatory approval. The Company concluded that the IPR&D is an identifiable intangible asset that would be accounted for as a single asset in a business combination. The Company

also qualitatively concluded that there is no fair value associated with any other assets included in the acquisition. Therefore, all of the consideration in the transaction was allocated to the IPR&D. As such, the Company concluded that substantially all of the fair value of the gross assets acquired was concentrated in the single IPR&D asset and the asset was not a business.

The Company is planning to use the acquired IPR&D technology to provide a solution to make peripheral nerve evaluation lead placement easier, faster, and more accurate. Although the acquired technology may have utility in other medical procedures, future development decisions for the acquired technology will be contingent upon the receipt of required regulatory approvals. As such, the acquired technology does not have an alternative future use at the acquisition date. In accordance with ASC 730, Research and Development, the Company concluded the entire purchase price for the asset acquisition was an expense on the acquisition date.

The consideration transferred at closing had an acquisition date fair value of $15.4 million based on a per share value of $58.34 on the acquisition date and was recognized immediately as IPR&D expense in the unaudited condensed consolidated statements of comprehensive income (loss) for the year ended December 31, 2023. The potential future milestone payment of $2.5 million, payable in either cash or shares of the Company's common stock, will become payable if the Company receives the FDA 510(k) clearance for the acquired IPR&D technology.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries: Axonics Europe, S.A.S., Axonics Modulation Technologies U.K. Limited, Axonics Modulation Technologies Australia Pty Ltd, Axonics Women's Health Limited, Bulkamid SARL, Axonics GmbH, and Contura, Inc. Intercompany accounts and transactions have been eliminated in consolidation.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). Certain prior year reported amounts have been reclassified to conform with the 2023 presentation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires the Company's management to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses, and related disclosures of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates, and such differences may be material to the consolidated financial statements. Such estimates and assumptions include the useful lives of property and equipment and intangible assets, the valuation of deferred income tax assets and liabilities, the valuation of contingent consideration liability, the valuation of stock-based compensation, the product returns reserve, the inventory obsolescence reserve and accounts receivable allowance for credit losses.

Revenue Recognition

Revenue recognized during the years ended December 31, 2023, 2022, and 2021 relates entirely to the sale of the Company's products to its customers and distributors.

The Company has revenue arrangements that consist of a single performance obligation. The Company recognizes revenue at the point in time when it transfers control of promised goods to its customers. Revenue is measured as the amount of consideration expected to be received in exchange for transferring goods. The amount of revenue that is recognized is based on the transaction price, which represents the invoiced amount and includes estimates of variable consideration such as discounts, where applicable. The Company also sells to distributors and applies the same policies as its revenue arrangements with customers, specifically that revenue is recognized at the point in time when it transfers control of promised goods to its distributors. The Company does not offer rights of return or price protection. The amount of variable consideration included in the transaction price may be constrained and is included only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Payment terms, typically less than three

months, do not include a significant financing component. The Company extends credit to its customers and distributors based upon an evaluation of their financial condition and credit history and generally requires no collateral. The Company does not have any contract balances related to product sales. The Company also does not have significant contract acquisition costs related to product sales.

In accordance with Company policy and based on the Company's historical experience, the allowance for product returns was $0.3 million and $0.2 million at December 31, 2023 and 2022, respectively, and is recorded as a reduction of gross revenue in its consolidated statements of comprehensive income (loss). Damaged or defective products are replaced at no charge under the Company's standard warranty. For the years ended December 31, 2023, 2022, and 2021, the replacement costs were $0.1 million, $0.2 million, and $0.2 million, respectively. The replacement costs are recorded within the sales and marketing expenses in its consolidated statements of comprehensive income (loss).

The Company offers its standard warranty to all customers. The Company does not sell any warranties on a standalone basis. The Company's warranty provides that its products are free of material defects and conform to specifications, and includes an offer to repair, replace or refund the purchase price of defective products. This assurance does not constitute a service and is not considered a separate performance obligation. The Company estimates warranty liability at the time of revenue recognition and records it as a charge to sales and marketing expense. The warranty liability as of December 31, 2023 and 2022 was $0.1 million and $0.1 million, respectively.

Shipping and handling costs incurred for the delivery of goods to customers and distributors are included in cost of goods sold. Amounts billed to customers and distributors for shipping and handling are included in net revenue.

The following table provides additional information pertaining to net revenue disaggregated by product and geographic market for the years ended December 31, 2023, 2022, and 2021 (in thousands):

	Years Ended December 31,		
	2023	2022	2021
SNM net revenue			
United States	$ 284,846	$ 216,861	$ 153,837
International markets	6,959	5,130	3,753
	$ 291,805	$ 221,991	$ 157,590
Bulkamid net revenue[1]			
United States	$ 59,036	$ 40,178	$ 12,660
International markets	15,538	11,533	10,040
	$ 74,574	$ 51,711	$ 22,700
Total net revenue	$ 366,379	$ 273,702	$ 180,290

(1) The acquisition of Bulkamid was completed on February 25, 2021. Reported revenue includes sales from February 26, 2021 onwards.

Allowance for Credit Losses

The Company makes estimates of the collectability of accounts receivable in accordance with Accounting Standards Update (ASU) 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The Company's estimate of future credit losses is made by management based upon historical bad debts, customer receivable balances, age of customer receivable balances, customers' financial conditions and reasonable forecasted economic trends. Despite the Company's efforts to minimize credit risk exposure, customers could be adversely affected if future economic and industry trends change in such a manner as to negatively impact their cash flows. As a result, the Company's future collection experience can differ significantly from historical collection trends. If the Company's customers experience a negative impact on their cash flows, it could have a material adverse effect on the Company's results of operations and financial condition.

The following table summarizes the changes in our allowance for credit losses (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Balance at beginning of period	$ 321	$ 355	$ 465
Write-offs	(15)	(75)	(12)
Bad debt expense (recoveries)	136	41	(98)
Balance at end of period	$ 442	$ 321	$ 355

Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments purchased with a maturity of three months or less. Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. At times, the cash and cash equivalent balances may exceed federally insured limits. The Company does not believe that this results in any significant credit risk as the Company's policy is to place its cash and cash equivalents in highly-rated financial institutions. The Company also holds cash in foreign banks that are not federally insured. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Restricted Cash

Restricted cash consists of amounts held by an escrow account. On September 18, 2023, the Company commenced an arbitration against AMF with Judicial Administration and Arbitration Services (JAMS) seeking, among other things, resolution that AMF's purported attempt to terminate the License Agreement, dated October 1, 2013, was ineffective and that the Company does not owe any royalties to AMF for the Company's F15 product and that the Company was not required to pay royalties on its F15 product under the License Agreement. AMF responded to the arbitration demand and asserted multiple claims. On October 5, 2023, the Company and AMF entered into an interim agreement while the arbitration proceedings were pending. Pursuant to this interim agreement, the Company agreed to deposit into an escrow account an amount equal to 4% of the net revenues previously received for sales of the Company's F15 product that are the subject of dispute. As of December 31, 2023, the Company has deposited approximately $12.7 million in the escrow account, and will continue to deposit the disputed 4% of net revenues of the Company's F15 product with interest into the escrow account during the pendency of the arbitration proceedings. The Company has paid and, under this interim agreement, will continue to pay 4% royalties on rechargeable products. While the Company believes that AMF's claims are without merit and intends to vigorously defend against those claims, there can be no assurance as to the outcome of the arbitration. For additional information, see Note 4.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet to the amounts reported within the consolidated statement of cash flows at December 31, 2023:

Cash and cash equivalents	$ 10
Restricted cash	1
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	$ 11

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. A three-level fair value hierarchy prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1: Inputs are unadjusted quoted prices in active markets for identical assets or liabilities.

- Level 2: Inputs are quoted prices for similar assets and liabilities in active markets or quoted prices for identical or similar instruments in markets that are not active and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
- Level 3: Inputs are unobservable inputs based on the Company's assumptions and valuation techniques used to measure assets and liabilities at fair value. The inputs require significant management judgment or estimation.

Level 1 investments include U.S. government and agency securities, which are valued based on prices readily available in the active markets in which those securities are traded. Level 2 investments include commercial paper and corporate notes, which is valued on a recurring basis based on inputs that are readily available in public markets or can be derived from information available in publicly quoted markets.

The Company's assessment of the significance of an input to the fair value measurement requires judgment, which may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels. The carrying amounts reported in the consolidated financial statements approximate the fair value for cash and cash equivalents, accounts receivable, and accounts payable, due to their short-term nature.

The purchase price of business acquisitions is primarily allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values on the acquisition date, with the excess recorded as goodwill.

The Company's business combination of Contura involved potential payment of future consideration that was contingent upon the achievement of certain product development milestones and/or contingent on the acquired business reaching certain performance milestones. A liability was recorded for the estimated fair value of the contingent consideration on the acquisition date. The fair value of the contingent consideration was remeasured at each reporting period, and the change in fair value was recognized within operating expenses in the consolidated statements of comprehensive income (loss).

On February 25, 2021, the Company acquired Contura Limited and its Bulkamid product, a urethral bulking agent indicated for the treatment of female SUI. In consideration for the acquisition, the Company paid approximately $141.3 million in cash and issued 1,096,583 shares of our common stock. The agreement also provided that the Company may pay an additional $35 million in the event Bulkamid sales in any consecutive 12-month period exceed $50 million (the Milestone) before December 31, 2024, with payment due within 50 business days following the quarter in which the Milestone has been met.

At March 31, 2023, the Milestone was met and payment was made during the year ended December 31, 2023. The fair value of contingent consideration of $32.6 million is reflected in other current liabilities in the Company's consolidated balance sheet at December 31, 2022.

The following table summarizes the changes in the fair value of recurring Level 3 fair value measurements during the years ended December 31, 2023 and 2022 (in thousands):

Liabilities		
Contingent consideration:		
December 31, 2021	$	10,370
Change in fair value included in net loss		22,230
December 31, 2022		32,600
Change in fair value included in net loss		2,400
Payment made	$	(35,000)
December 31, 2023	$	—

There were no transfers between Levels 1, 2 or 3 for the periods presented.

Investment Securities

The Company classifies its investment securities as available-for-sale. Those investments in debt securities with maturities less than 12 months at the balance sheet date are considered short-term investments. Those investments in debt securities with maturities greater than 12 months at the balance sheet date are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based on the fair value hierarchy (Level 1 and Level 2 inputs in the fair value hierarchy), and consists primarily of commercial paper, corporate notes and U.S. government and agency securities. Unrealized gains or losses, deemed temporary in nature, are reported as other comprehensive income (loss) within the consolidated statements of comprehensive income (loss). There were no unrealized gains or losses during the years ended December 31, 2023, 2022, and 2021.

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to net income (loss) and the corresponding establishment of a credit loss allowance for the security. Premiums (discounts) are amortized (accreted) over the life of the related security as an adjustment to yield using the straight-line interest method. Dividend, accretion and interest income are recognized when earned. Realized gains or losses are included in net loss and are derived using the specific identification method for determining the cost of securities sold.

The following table presents the fair value hierarchy for those assets measured at fair value on a recurring basis as of December 31, 2023 and 2022 (in thousands):

	Fair Value Measurements at December 31, 2023			
Assets[1]:	**Level 1**	**Level 2**	**Level 3**	**Total**
Commercial paper	$ —	$ 179,881	$ —	$ 179,881
Corporate notes	—	18,279	—	18,279
U.S. government and agency securities	91,703	—	—	91,703
	$ 91,703	$ 198,160	$ —	$ 289,863

(1) As of December 31, 2023, commercial paper investments of $49.7 million are included in cash and cash equivalents on the consolidated balance sheets, as the investments had a maturity of three months or less from the date of purchase.

	Fair Value Measurements at December 31, 2022			
Assets[1]:	**Level 1**	**Level 2**	**Level 3**	**Total**
Commercial paper	$ —	$ 175,548	$ —	$ 175,548
Corporate notes	—	4,675	—	4,675
U.S. government and agency securities	75,212	—	—	75,212
	$ 75,212	$ 180,223	$ —	$ 255,435

(1) As of December 31, 2022, commercial paper investments of $131.1 million, U.S. government and agency securities of $4.0 million, and corporate notes of $2.0 million are included in cash and cash equivalents on the consolidated balance sheets, as the investments had a maturity of three months or less from the date of purchase.

The Company holds investments in marketable debt securities that are classified and accounted for as cash equivalents or available-for-sale and are remeasured on a recurring basis. All of the Company's available-for-sale debt securities are classified on the consolidated balance sheet as cash equivalents or short-term investments. The following table summarizes the Company's cash equivalents and investments in available-for-sale debt securities by significant investment category as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash equivalents:				
Commercial paper	$ 49,714	$ —	$ —	$ 49,714
Corporate notes	—	—	—	—
U.S. government and agency securities	—	—	—	—
Total cash equivalents	$ 49,714	$ —	$ —	$ 49,714
Short-term investments:				
Commercial paper	$ 130,161	$ 9	$ (3)	$ 130,167
Corporate notes	18,272	18	(11)	18,279
U.S. government and agency securities	91,670	40	(7)	91,703
Total short-term investments	$ 240,103	$ 67	$ (21)	$ 240,149
Total	$ 289,817	$ 67	$ (21)	$ 289,863

	December 31, 2022			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash equivalents:				
Commercial paper	$ 131,075	$ —	$ —	$ 131,075
Corporate notes	2,013	—	—	2,013
U.S. government and agency securities	3,982	—	—	3,982
Total cash equivalents	$ 137,070	$ —	$ —	$ 137,070
Short-term investments:				
Commercial paper	$ 44,473	$ —	$ —	$ 44,473
Corporate notes	2,664	—	(2)	2,662
U.S. government and agency securities	71,342	6	(118)	71,230
Total short-term investments	$ 118,479	$ 6	$ (120)	$ 118,365
Total	$ 255,549	$ 6	$ (120)	$ 255,435

Inventory, Net

Inventory is stated at the lower of cost or net realizable value, with cost computed on a first-in, first-out basis. The Company reduces the carrying value of inventory for items that are potentially excess, obsolete, or slow-moving based on changes in customer demand, technology developments, or other economic factors.

The Company capitalizes inventory produced for commercial sale. The Company capitalizes manufacturing costs as inventory following both the receipt of regulatory approval from regulatory bodies and the Company's intent to commercialize. Costs associated with developmental products prior to satisfying the Company's inventory capitalization criteria are charged to research and development expenses as incurred.

Products that have been approved by certain regulatory authorities may also be used in clinical programs to assess the safety and efficacy of the products for usage that have not been approved by the FDA or other regulatory authorities. The form of product utilized for both commercial and certain clinical programs that are identical are included as inventory with an "alternative future use" as defined in ASC 730, Research and Development. Component materials and purchased products associated with clinical development programs are included in inventory and charged to research and development expenses when the product enters the research and development process and no longer can be used for commercial purposes and, therefore, does not have an "alternative future use."

For products that are under development and have not yet been approved by regulatory authorities, purchased component materials are charged to research and development expenses when the inventory ownership transfers to the Company.

The Company analyzes inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its net realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of the Company's SNM systems is subject to strict quality control, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to the Company's inventory values. The Company also applies judgment related to the results of quality tests that are performed throughout the production process, as well as the understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre- and post-production processes, and the Company continually gathers information regarding product quality for periods after the manufacturing date. The Company's products currently have a maximum estimated shelf-life range of 12 to 36 months and based on sales forecasts, the Company expects to realize the carrying value of the product inventory. In the future, reduced demand, quality issues, or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

The determination of whether inventory costs will be realizable or not requires estimates by the Company's management. A critical input in this determination is future expected inventory requirements based on internal sales forecasts. Management then compares these requirements to the expiry dates of inventory on hand. To the extent that inventory is expected to expire prior to being sold, management will write down the value of inventory.

As of December 31, 2023, the Company had $48.9 million, $10.5 million and $20.5 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, net of reserves of $2.3 million. As of December 31, 2022, the Company had $30.4 million, $5.7 million and $19.7 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, net of reserves of $0.5 million.

Foreign Currency Translation

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Revenue and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' equity in accumulated other comprehensive gain or loss until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss). As of December 31, 2023 and 2022, all foreign currency translation gains (losses) have been unrealized and included in accumulated other comprehensive income (loss). Accumulated other comprehensive income (loss) consists entirely of losses or gains from translation of foreign subsidiaries at December 31, 2023 and 2022.

Customer and Vendor Concentration

As of December 31, 2023 and 2022, there were no customers who accounted for over 10% of the Company's consolidated accounts receivable. As of December 31, 2023 and 2022, there were three vendors and one vendor, respectively, who accounted for over 10% of the Company's consolidated accounts payable. As of December 31, 2023, 2022, and 2021, there were no customers who accounted for over 10% of the Company's consolidated net revenue. As of December 31, 2023, 2022, and 2021, there were three, three, and three vendors, respectively, who accounted for over 10% of the Company's inventory-related purchases.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are amortized over the lesser of the life of the lease or the useful life of the improvements. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations.

Goodwill

Goodwill represents the excess purchase price over the fair values of both tangible and intangible assets acquired less the liabilities assumed. Goodwill is tested for impairment at the reporting unit level by comparing the reporting unit's carrying amount to the fair value of the reporting unit. The fair values are estimated using an income and discounted cash flow approach. The Company evaluates its goodwill on an annual basis in the fourth quarter or more frequently if it believes indicators of impairment exist. The Company assesses qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount or performs an annual impairment test. When tested quantitatively, the Company compares the fair value of the applicable reporting unit with its carrying value. In making this assessment, management relies on a number of factors, including expected future operating results, business plans, economic projections, anticipated future cash flows, business trends and declines in the Company's market capitalization. The Company estimates the fair value of its reporting unit using a combination of the discounted cash flow and income approaches. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the amount by which the carrying value exceeds the fair value is recognized as an impairment loss. There has been no goodwill impairment charges during the years ended December 31, 2023, 2022, and 2021.

Intangible Assets

Patent license asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The additional field-of-use was provided in exchange for 50,000 shares of Series A preferred stock, the fair value of which was $1.0 million in 2013. The intangible asset was recorded at its fair value of $1.0 million at the date contributed. In connection with the initial public offering, such shares of Series A preferred stock were converted into common stock. Amortization of this asset is recorded over the shorter of the patent or legal life on a straight-line basis. The weighted-average amortization period was 8.71 years. The asset has been fully amortized as of December 31, 2022.

Exclusive license asset

The intangible asset represents exclusive rights to existing technologies and development services from Micro Systems Engineering, Inc. pursuant to an agreement entered into on March 2, 2021. The rights and services were provided in exchange for 65,594 shares of common stock, the fair value of which was $3.6 million upon transfer. The intangible asset was recorded at its fair value of $3.3 million at the date of the agreement, with the difference of $0.3 million recorded as a vendor credit in accounts payable in the consolidated balance sheets. Amortization of this asset is recorded over the four-year term of the agreement on a straight-line basis. The Company will review the intangible asset for impairment whenever an impairment indicator exists. There has been no intangible asset impairment charges during the years ended December 31, 2023, 2022, and 2021.

Contura acquisition

The intangible assets represent technology, trade names and trademarks, and customer relationships acquired from Contura on February 25, 2021. The trade names and trademarks have an indefinite life. The straight-line method over the period of estimated benefit is used to amortize technology. ASC 350-30-35-3, General Intangibles other than Goodwill, states that customer relationships generally dissipate at a more rapid rate in the earlier periods following a company's succession to these relationships, with the rate of attrition declining over time. As such, the accelerated method is used to amortize customer relationships. The Company will review the intangible assets for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges during the year ended December 31, 2023. During the year ended December 31, 2022, as Bulkamid SARL

ceased sales operations and did not recognize revenue and does not expect to recognize revenue in future periods, the Company wrote off the customer relationships intangible asset of $0.3 million related to this entity. The impairment expense was recorded within the general and administrative expenses in its consolidated statements of comprehensive income (loss).

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net cash flows that the assets are expected to generate. If said assets are considered to be impaired, the impairment that would be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There has been no intangible asset impairment charges during the years ended December 31, 2023 and 2021. There has been $0.3 million of intangible asset impairment charges during the year ended December 31, 2022.

Indefinite-lived intangible assets are tested for impairment annually in the fourth quarter of the fiscal year and whenever events or changes in circumstances indicate that the carrying amount may be impaired. Impairment is calculated as the excess of the asset's carrying value over its fair value. Fair value is generally determined using a discounted future cash flow analysis. There have been no impairments to indefinite-lived intangible assets during the years ended December 31, 2023, 2022 and 2021.

Leases

In accordance with ASU 2016-02, Leases (Topic 842), components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components. Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only. Topic 842 allows for the use of judgment in determining whether the assumed lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset.

Operating lease right-of-use (ROU) assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate, which is the rate for a fully collateralized amortizing loan with the same maturity as the lease term in similar economic environment, based on the information available at commencement date in determining the present value of future payments. The operating lease ROU assets also include any lease payments made and excludes lease incentives and initial direct costs incurred, and are included in other assets in the Company's consolidated balance sheets. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include employee compensation, including stock-based compensation, product development, including testing and engineering, royalty expense, and clinical studies to develop and support the Company's products, including clinical study and registry management and monitoring, payments to clinical investigators, and data management. Other research and development expenses include consulting and advisory fees, royalty expense, travel expenses, and equipment-related expenses and other miscellaneous office and facilities expenses related to research and development programs.

Advertising Expense

The Company expenses advertising costs as they are incurred. During the years ended December 31, 2023, 2022, and 2021, advertising expense totaled $19.5 million, $20.6 million and $7.8 million, respectively, and are recorded within the sales and marketing expenses in its consolidated statements of comprehensive income (loss).

Income Taxes

The Company accounts for income taxes using the asset and liability method to compute the difference between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. The Company has net deferred tax assets in certain jurisdictions. The realization of these deferred tax assets is dependent upon the Company's ability to generate sufficient taxable income in future years. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. The Company evaluates the recoverability of the deferred tax assets annually and maintains a full valuation allowance on its U.S. net deferred tax assets and a partial valuation allowance on certain foreign deferred tax assets. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The Company is subject to transfer pricing and other tax regulations designed to ensure that appropriate levels of income are reported as earned by the Company's U.S. and foreign entities and are taxed accordingly. In the normal course of business, the Company is audited by federal, state and foreign tax authorities, and subject to inquiries from those tax authorities regarding the amount of taxes due. These inquiries may relate to the timing and amount of deductions and the allocation of income among various tax jurisdictions. The Company's policy is to recognize interest and penalties related to unrecognized tax benefits, if any, in income tax expense.

Stock-Based Compensation

The Company measures the cost of employee and non-employee services in exchange for an award of equity instruments based on the grant-date fair value of the award and recognizes compensation cost over the requisite service period (typically the vesting period), generally three or four years. Forfeitures are estimated at the time of the grant and revised in subsequent periods to reflect differences between the estimates and the number of shares that actually become exercisable.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options (as of the date of grant) that have service conditions for vesting. Stock options and restricted shares awards vest based on service conditions, typically over three or four years.

The Company also grants shares of performance-based restricted stock units that typically vest after one year only if the Company has also achieved certain performance objectives as defined and approved by the Company's board of directors. The fair value of performance awards is determined based on the Company's stock price at the date of grant and expensed over the performance period based on the probability of achieving the performance objectives. If such targets are not met or service is not rendered for the requisite service period, no compensation cost is recognized, and any recognized compensation cost in prior periods will be reversed. In addition, the Company also grants market-based RSUs that have combined market conditions and service conditions for vesting, for which the Company uses the Monte Carlo valuation model to value equity awards (as of the date of grant). Compensation cost is not adjusted if the market condition is not met, as long as the requisite service is provided.

Net Loss per Share of Common Stock

Basic net loss per share of common stock is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, common stock options, unvested RSAs and RSUs are considered to be potentially dilutive securities. Because the Company has reported a net loss in all periods presented, diluted net loss per share of common stock is the same as basic net loss per share of common stock for those periods.

For the years ended December 31, 2023, 2022, and 2021, there were 2,132,330, 2,328,525, and 2,444,444 potentially dilutive weighted-average shares, respectively, that were not included in the computation of diluted weighted-average shares of common stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss.

Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined it operates in one segment, the development and commercialization of innovative and minimally invasive products to treat bladder and bowel dysfunction. Geographically, the Company sells over 90% of its products to customers in the United States. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board (FASB) issued ASU 2023-09, Improvements to Income Tax Disclosures (ASU 2023-09). The guidance is intended to improve income tax disclosure requirements by requiring (i) consistent categories and greater disaggregation of information in the rate reconciliation and (ii) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. This guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted, and is required to be applied prospectively with the option of retrospective application. The Company is evaluating the impact of the standard on its financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07 to require the disclosure of segment expenses if they are (i) significant to the segment, (ii) regularly provided to the CODM, and (iii) included in each reported measure of a segment's profit or loss. Public entities will be required to provide this disclosure quarterly. In addition, this ASU requires an annual disclosure of the CODM's title and a description of how the CODM uses the segment's profit/loss measure to assess segment performance and to allocate resources. This guidance is effective for annual periods beginning after December 15, 2023 and interim periods beginning after December 15, 2024, with early adoption permitted, and is required to be applied retrospectively to all prior periods presented in the financial statements. The Company is evaluating the impact of the standard on its financial statements and related disclosures.

Note 2. Property and Equipment, Net

Property and equipment, net consists of the following (in thousands) at:

	December 31,	
	2023	**2022**
Equipment	$ 3,169	$ 2,645
Computer hardware and software	3,638	3,282
Tools and molds	2,315	1,735
Leasehold improvements	4,573	4,449
Furniture and fixtures	1,876	1,810
Construction in progress	6,054	413
	21,625	14,334
Less: accumulated depreciation and amortization	(10,865)	(7,536)
	$ 10,760	$ 6,798

Depreciation expense of property and equipment was $3.4 million, $2.3 million, and $1.9 million for the years ended December 31, 2023, 2022, and 2021, respectively. The construction in progress balance primarily relates to the construction costs for the new principal executive offices and for general office, manufacturing, and warehousing space under an operating lease entered into in April 2023.

Note 3. Goodwill and Intangible Assets

The change in the carrying amount of goodwill during the years ended December 31, 2023 and 2022 included the following (in thousands):

December 31, 2021	$ 105,510
Foreign currency translation adjustment	(11,096)
December 31, 2022	94,414
Foreign currency translation adjustment	5,003
December 31, 2023	$ 99,417

Intangible assets as of December 31, 2023 included the following (in thousands):

		December 31, 2023				
	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Impairment	Foreign currency translation adjustment	Intangible Assets, Net
Patent license asset	8.71 years	$ 1,000	$ (1,000)	$ —	$ —	$ —
Exclusive license asset	4 years	3,300	(2,420)	—	—	880
Technology	12 years	81,100	(19,236)	—	(6,140)	55,724
Trade names and trademarks	Indefinite	19,700	—	—	(1,482)	18,218
Customer relationships	12 years	11,400	(3,837)	(287)	(723)	6,553
		$ 116,500	$ (26,493)	$ (287)	$ (8,345)	$ 81,375

Intangible asset as of December 31, 2022 included the following (in thousands):

		December 31, 2022				
	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Impairment	Foreign currency translation adjustment	Intangible Assets, Net
Patent license asset	8.71 years	$ 1,000	$ (1,000)	$ —	$ —	$ —
Exclusive license asset	4 years	3,300	(1,540)	—	—	1,760
Technology	12 years	81,100	(12,496)	—	(9,141)	59,463
Trade names and trademarks	Indefinite	19,700	—	—	(2,398)	17,302
Customer relationships	12 years	11,400	(2,393)	(287)	(992)	7,728
		$ 116,500	$ (17,429)	$ (287)	$ (12,531)	$ 86,253

The Company recorded expense for the amortization of intangible assets of $9.1 million, $9.4 million, and $7.2 million, respectively, during the years ended December 31, 2023, 2022, and 2021. The estimated future amortization expense as of December 31, 2023, is as follows (in thousands):

2024	$ 8,962
2025	7,927
2026	7,783
2027	7,645
2028	7,512

Note 4. Commitments and Contingencies

Operating Leases

In August 2014, the Company entered into a five-year operating lease for approximately 12,215 square feet of office space beginning on November 1, 2014, and expiring on October 31, 2019. In June 2019, the lease was amended to extend the expiration date to October 31, 2020. In September 2020, the lease was amended to extend the expiration date to July 31, 2022. In December 2021, the lease was amended to extend the expiration date to January 31, 2028, and in April 2023, the lease was amended to reduce the expiration date to March 31, 2024. Upon the execution of the amendments, which were deemed to be a lease modification, the Company reassessed the lease liability using the incremental borrowing rate for a collateralized asset of the same remaining term at the modification date and adjusted the carrying amount of ROU assets by the amount of the remeasurement of the liability. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term.

The Company entered into an operating lease for approximately 25,548 square feet of office space beginning on August 1, 2018, and expiring on October 31, 2027. In April 2023, the lease was amended to reduce the expiration date to December 31, 2024 and in September 2023, the lease was amended to extend the expiration date to July 1, 2025. Upon the execution of the amendment, which was deemed to be a lease modification, the Company reassessed the lease liability using the incremental borrowing rate for a collateralized asset of the same remaining term at the modification date and adjusted the carrying amount of ROU assets by the amount of the remeasurement of the liability. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Under the terms of the lease, the base rent payable with respect to each renewal term will be equal to the prevailing market rental rent as of the commencement of the applicable renewal term. In the event of a default of certain of the Company's obligations under the lease, the Company's landlord would have the right to terminate the lease.

In June 2019, the Company entered into an eight-year operating lease for approximately 32,621 square feet of office space beginning on January 15, 2020 and expiring on January 31, 2028. In April 2023, the lease was amended to reduce the expiration date to March 31, 2024 and in September 2023, the lease was amended to extend the expiration date to December 31, 2024. Upon the execution of the amendment, which was deemed to be a lease modification, the Company reassessed the lease liability using the incremental borrowing rate for a collateralized asset of the same remaining term at the modification date and adjusted the carrying amount of ROU assets by the amount of the remeasurement of the liability. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. The Company uses these premises as its new principal executive offices and for general office space. The Company is utilizing its other currently-leased spaces to conduct the training of its sales team and for manufacturing purposes. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Under the terms of the lease, the base rent payable with respect to each renewal term will be equal to the prevailing market rental rent as of the commencement of the applicable renewal term. In the event of a default of certain of the Company's obligations under the lease, the Company's landlord would have the right to terminate the lease.

In August 2020, the Company entered into a 38-month operating lease for approximately 5,693 square feet of warehouse space beginning on October 15, 2020 and expiring on December 31, 2023. In April 2023, the lease was amended to extend the expiration date to December 31, 2024 and in September 2023, the lease was amended to extend the expiration date to July 1, 2025. Upon the execution of the amendment, which was deemed to be a lease modification, the Company reassessed the lease liability using the incremental borrowing rate for a collateralized asset of the same remaining term at the modification date and adjusted the carrying amount of ROU assets by the amount of the remeasurement of the liability. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. The Company uses these premises for general warehouse space.

In March 2022, the Company entered into an 18-month operating lease for approximately 3,276 square feet of warehouse space beginning on July 1, 2022 and expiring on December 31, 2023. In April 2023, the lease was amended to extend the expiration date to December 31, 2024 and in September 2023, the lease was amended to extend the expiration date to July 1, 2025. Upon the execution of the amendment, which was deemed to be a lease modification, the Company reassessed the lease liability using the incremental borrowing rate for a collateralized asset of the same remaining term at the modification date and adjusted the carrying amount of ROU assets by the amount of the remeasurement of the liability. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. The Company uses these premises for general warehouse space.

In April 2023, the Company entered into a 120-month operating lease for approximately 145,960 square feet of office and warehouse space beginning on April 1, 2024 and expiring on March 31, 2034. The Company will use these premises as its new principal executive offices and for general office, manufacturing, and warehousing space. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. The Company has a renewal option to extend the term of the lease for a period of five years beyond the initial term. Under the terms of the lease, the base rent payable with respect to each renewal term will be equal to the prevailing market rental rent as of the commencement of the applicable renewal term. In the event of a default of certain of the Company's obligations under the lease, the Company's landlord would have the right to terminate the lease. The lease commenced on November 1, 2023, which was the date the Company was provided access to the leased property and control over its use. Therefore, the Company recorded $21.9 million of ROU assets and $23.1 million of operating lease liabilities related to this lease.

During the years ended December 31, 2023, 2022, and 2021, ROU assets obtained in exchange for new operating lease liabilities were $21.9 million, $0.1 million, and $1.0 million, respectively. As of December 31, 2023 and 2022, the ROU assets had a balance of $22.5 million and $6.2 million, respectively. The operating lease ROU assets are included within the Company's non-current other assets, and lease liabilities are included in current or noncurrent liabilities in the Company's consolidated balance sheets. During the years ended December 31, 2023, 2022, and 2021, cash paid for amounts included in operating lease liabilities was $2.5 million, $2.1 million, and $2.0 million, respectively. Amortization of the ROU assets was $0.9 million, $1.0 million, and $1.0 million for the years ended December 31, 2023, 2022, and 2021, respectively. As of December 31, 2023 and 2022, the weighted-average remaining lease term for the Company's operating leases was 9.6 years and 4.9 years, respectively. The weighted-average incremental borrowing rate for a collateralized asset of the same remaining term used to determine the present value of the Company's operating leases' future payments was 5.9% and 7.1%, respectively.

Total lease costs for the years ended December 31, 2023, 2022, and 2021 are as follows (in thousands):

	December 31,		
	2023	2022	2021
Lease cost			
Operating lease cost	$ 2,785	$ 2,131	$ 2,107
Short-term lease cost	85	80	95
Variable lease cost	527	203	191
Amortization of net lease liabilities	(1,667)	—	—
Total lease cost	$ 1,730	$ 2,414	$ 2,393

Payments of operating lease liabilities as of December 31, 2023, are as follows (in thousands):

2024	$ 2,296
2025	4,388
2026	4,011
2027	4,151
2028	4,291
Thereafter	25,130
	44,267
Less: imputed interest	(16,650)
	27,617
Less: operating lease liabilities, current portion	(1,777)
Operating lease liabilities, net of current portion	$ 25,840

License Agreement

In October 2013, the Company entered into the License Agreement, pursuant to which AMF, a Company stockholder, licensed the Company certain patents and know-how (collectively, the AMF IP) relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (collectively, the AMF Licensed Products). Under the License Agreement, for each calendar year beginning in 2018, the Company is obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to the Company by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) the Minimum Royalty, payable quarterly. The Minimum Royalty automatically increases each year after 2018, subject to a maximum amount of $200,000 per year. The Company recorded related royalties of $2.5 million, $3.3 million, and $6.3 million during the years ended December 31, 2023, 2022, and 2021, respectively. Royalty expense is included in operating expenses in the consolidated statements of comprehensive income (loss). Accrued royalties of $0.8 million and $0.6 million as of December 31, 2023 and 2022, respectively, are included within accrued liabilities in the Company's consolidated balance sheets. Royalty expense is declining because the Company's F15 recharge-free SNM device is not an AMF Licensed Product that requires the payment of a royalty to AMF, including because it is not covered by any AMF patents licensed to the Company and for other reasons. For additional information, see Legal Matters section below.

Legal Matters

In addition to the matters described below, the Company may, from time to time, become a party to legal proceedings. Such matters are subject to many uncertainties and to outcomes of which the financial impacts are not

predictable with assurance and that may not be known for extended periods of time. When management has assessed that a loss is probable and an amount can be reasonably estimated, the Company records a liability.

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 the Company 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. The Company refers to this matter as the Medtronic Litigation. The complaint asserts that the Company's 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 the Company has infringed and is infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) a permanent injunction preventing the Company 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 Axonics 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 for before the PTAB. The Company believes the allegations of the Medtronic Affiliates are without merit and is vigorously defending itself against them. The Company is unable to predict the likelihood of success of the claims of the Medtronic Affiliates against the Company or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and require the Company to dedicate significant financial resources and management resources to its defense. An adverse ruling against the Company could materially and adversely affect its business, financial position, results of operations or cash flows and could also result in reputational harm. Even if the Company is 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.

On September 18, 2023, the Company commenced an arbitration against AMF with JAMS seeking, among other things, resolution that AMF's purported attempt to terminate the License Agreement, dated October 1, 2013, was ineffective and that the Company does not owe any royalties to AMF for the Company's F15 product and the Company was not required to pay royalties on its F15 product under the License Agreement. AMF responded to the arbitration demand and asserted multiple claims. On October 5, 2023, the Company and AMF entered into an interim agreement while the arbitration proceedings are pending. Pursuant to this interim agreement, the Company agreed to deposit into an escrow account an amount equal to 4% of the net revenues previously received for sales of the Company's F15 product that are the subject of dispute, which the Company has determined is approximately $16 million from January 1, 2022 through December 31, 2023, with interest, and will continue to deposit the disputed 4% of net revenues of the Company's F15 product with interest into the escrow account during the pendency of the arbitration proceedings. The Company has paid and, under this interim agreement, will continue to pay 4% royalties on rechargeable products. While the loss from this contingency is reasonably possible, the Company does not believe that such loss is probable. The Company believes that AMF's claims are without merit and intends to vigorously defend against those claims, however, there can be no assurance as to the outcome of the arbitration.

Note 5. Debt

In February 2018, the Company entered into the Loan and Security Agreement with Silicon Valley Bank, providing for a term loan (the Term Loan).

In January 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to the Term Loan were paid in full. The unamortized debt issuance costs of $0.4 million were expensed and recognized as interest expense.

In February 2021, the Company entered into another Loan and Security Agreement (the Loan and Security Agreement) with Silicon Valley Bank, under which the Company obtained a loan in the principal amount of $75 million.

In June 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to this loan were paid in full. The unamortized debt issuance costs of $4.4 million were expensed and recognized as interest expense.

Note 6. Stockholders' Equity

Preferred Stock

As of December 31, 2023, the Company is authorized to issue 10,000,000 shares of preferred stock with a par value of $0.0001 per share. No preferred stock is issued or outstanding as of December 31, 2023 and 2022.

Common Stock

The following summarizes the rights of holders of our common stock:

Voting

The holders of our common stock are entitled to one vote per share. The number of authorized shares of common stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of our capital stock entitled to vote, irrespective of the provisions of Section 242(b)(2) of the Delaware General Corporation Law (DGCL).

Dividends

Subject to preferences that may be applicable to the holders of outstanding shares of preferred stock and subject to applicable law, dividends may be declared and paid on the holders of our common stock when and as determined by our board of directors out of assets legally available for dividends.

As a Delaware corporation, the Company will be subject to certain restrictions on dividends under the DGCL. Generally, a Delaware corporation may only pay dividends either out of "surplus" or out of the current or the immediately preceding year's net profits. Surplus is defined as the excess, if any, at any given time, of the total assets of a corporation over its total liabilities and statutory capital. The value of a corporation's assets can be measured in a number of ways and may not necessarily equal their book value.

Liquidation Rights

Upon our voluntary or involuntary liquidation, dissolution or winding up, after satisfaction of all our liabilities and the payment of any liquidation preference of any outstanding preferred stock, the holders of shares of common stock will be entitled to share in all of our assets legally remaining for distribution after payment of all debt and other liabilities, subject to preferences that may be applicable to the holders of outstanding shares of preferred stock.

Redemption Rights

There are no redemption or sinking fund provisions applicable to our common stock.

Preemptive Rights and Conversion Rights

There are no preemptive or conversion rights applicable to our common stock.

Stock-Based Compensation Expense

Stock-based compensation expense included in the Company's consolidated statements of comprehensive income (loss) is allocated as follows (in thousands):

	Years Ended December 31,		
	2023	**2022**	**2021**
Research and development	$ 9,362	$ 6,734	$ 5,980
General and administrative	11,687	7,965	8,079
Sales and marketing	23,487	17,319	11,105
	$ 44,536	$ 32,018	$ 25,164

Stock Option Activity

2014 Stock Option Plan

In 2014, the Company established its 2014 Stock Option Plan (the 2014 Plan), which provides for the granting of stock options to employees, directors, and consultants of the Company. The 2018 Omnibus Incentive Plan was adopted upon our IPO and replaced the 2014 Stock Option Plan for future grants. As of December 31, 2023 and 2022, there were no stock options available for grant under the 2014 Plan.

2018 Omnibus Incentive Plan

On October 18, 2018, the Company adopted the 2018 Omnibus Incentive Plan (the 2018 Plan), under which the Company may grant cash and equity incentive awards to eligible service providers to attract, motivate and retain the talent for which it competes. The 2018 Plan provides for awards based on shares of the Company's common stock. Subject to adjustment by the Company's board of directors, the total number of shares authorized to be awarded under the 2018 Plan may not exceed 7,088,581. As of December 31, 2023, there were 1,920,160 shares available for grant under the 2018 Plan, respectively.

The Company had shares of common stock reserved for future issuance as follows at:

	December 31,	
	2023	**2022**
Options outstanding under the 2014 Plan	160,863	184,104
Options and restricted stock units outstanding under the 2018 Plan	884,617	1,045,924
Options and restricted stock-based awards remaining under the 2018 Plan for future issuance	1,920,160	2,694,622
	2,965,640	3,924,650

The fair value of each stock option is measured as of the date of grant, and compensation expense is recognized over the period during which the recipient renders the required services to the Company (typically the vesting period). Stock-based compensation expense recognized is based on the estimated number of stock options that are expected to ultimately become exercisable. Forfeitures are estimated at the time of the grant and revised in subsequent periods to reflect differences between the estimates and the number of shares that become exercisable.

The option awards issued under the 2014 and 2018 Plans were measured based on fair value. The Company's fair value calculations were made using the Black-Scholes option pricing model with the following assumptions:

	Years Ended December 31,		
	2023	2022	2021
Expected term (in years)	—	—	5.46 - 6.00
Stock volatility	—	—	63.49%
Risk-free interest rate	—	—	0.53% - 1.16%
Dividend rate	—	—	—

The Company used the simplified method of determining the expected term of stock options as the Company believes this represents the best estimate of the expected term of a new option. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have sufficient trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments, whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The assumptions regarding the expected term of the options and the expected volatility of the stock price are subjective, and these assumptions have a significant effect on the estimated fair value amounts. There were no stock option grants for the years ended December 31, 2023 and 2022. The weighted-average grant date fair value of options granted was $32.93 for the year ended December 31, 2021.

As of December 31, 2023, there was $0.1 million of total unrecognized compensation cost related to unvested stock options that is expected to be recognized over a weighted-average period of approximately 1.1 years.

The following table summarizes stock option activity under the 2014 and 2018 Plans (in thousands, except share and per share data):

	Number of Options	Weighted-Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at December 31, 2020	1,955,243	$ 16.01	
Options granted	46,000	58.07	
Options exercised	(522,495)	12.60	$ 24,455 (1)
Options forfeited	(50,856)	29.64	
Outstanding at December 31, 2021	1,427,892	18.13	
Options exercised	(364,352)	15.54	$ 18,251 (1)
Options forfeited	(16,930)	31.80	
Outstanding at December 31, 2022	1,046,610	18.81	
Options exercised	(219,763)	19.34	$ 9,076 (1)
Options forfeited	(12,067)	31.57	
Outstanding at December 31, 2023	814,780	$ 18.47	$ 35,652 (2)
Options exercisable at December 31, 2023	810,400	$ 18.25	$ 35,642 (2)

(1) Represents the total difference between the Company's closing stock price at the time of exercise and the stock option exercise price, multiplied by the number of options exercised.

(2) Represents the total difference between the Company's closing stock price on the last trading day of 2023 and the stock option exercise price, multiplied by the number of in-the-money options as of December 31, 2023. The amount of intrinsic value will change based on the fair market value of the Company's stock.

The weighted-average remaining contractual term of options outstanding and exercisable is 5.2 years at December 31, 2023.

Restricted Shares Awards Activity

As of December 31, 2023, there was $54.1 million of total unrecognized compensation cost related to unvested RSAs that is expected to be recognized over a weighted-average period of approximately 1.9 years.

The following table summarizes RSAs activity:

	Number of Restricted Shares Awards	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2020	817,183	$ 31.70
Restricted shares awards granted	638,936	57.90
Restricted shares awards vested	(235,560)	31.19
Restricted shares awards forfeited	(118,525)	40.33
Outstanding at December 31, 2021	1,102,034	46.07
Restricted shares awards granted	683,354	56.69
Restricted shares awards vested	(351,946)	42.15
Restricted shares awards forfeited	(112,576)	50.50
Outstanding at December 31, 2022	1,320,866	52.23
Restricted shares awards granted	635,766	57.28
Restricted shares awards vested	(540,441)	48.86
Restricted shares awards forfeited	(112,487)	54.88
Outstanding at December 31, 2023	1,303,704	$ 55.86

Restricted Stock Units Activity

As of December 31, 2023, there was $3.7 million of total unrecognized compensation cost related to unvested RSUs that is expected to be recognized over a weighted-average period of approximately 0.9 years.

The following table summarizes RSUs activity:

	Number of Restricted Stock Units	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2020	207,101	$ 23.49
Restricted stock units granted	212,417	43.62
Restricted stock units vested	(169,054)	19.89
Outstanding at December 31, 2021	250,464	42.99
Restricted stock units granted	201,884	38.75
Restricted stock units vested	(268,930)	35.88
Outstanding at December 31, 2022	183,418	48.74
Restricted stock units granted	286,750	65.44
Restricted stock units vested	(215,968)	50.71
Restricted stock units forfeited	(23,500)	$ 75.07
Outstanding at December 31, 2023	230,700	$ 70.20

Note 7. Income Taxes

The components of net (loss) income before income tax expense (benefit) were as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Domestic	$ 1,916	$ (24,466)	$ (56,105)
Foreign	(10,660)	(37,850)	(23,180)
Total	$ (8,744)	$ (62,316)	$ (79,285)

The components of the income tax expense (benefit) were as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Current:			
Federal	$ —	$ —	$ —
State	409	76	211
Foreign	1,433	174	26
Total current income tax expense	$ 1,842	$ 250	$ 237
Deferred:			
Federal	$ —	$ —	$ (422)
State	—	—	(117)
Foreign	(4,498)	(2,868)	1,084
Total deferred income tax (benefit) expense	$ (4,498)	$ (2,868)	$ 545
Total	$ (2,656)	$ (2,618)	$ 782

The reconciliation between the Company's effective tax rate and the statutory tax rate is as follows:

	Years Ended December 31,		
	2023	2022	2021
Tax at statutory federal rate	21.0 %	21.0 %	21.0 %
State tax, net of federal benefit	(0.5)%	1.0 %	3.8 %
Excess tax benefits related to stock-based compensation	46.6 %	8.3 %	9.4 %
Non-deductible stock-based compensation	(75.1)%	(1.7)%	(1.4)%
Tax rate change	9.2 %	1.0 %	(5.2)%
Net operating loss adjustments	— %	— %	(7.9)%
R&D tax credit, net of reserve	40.3 %	4.1 %	6.1 %
Change in valuation allowance	(0.9)%	(19.6)%	(24.5)%
Change in fair value of contingent consideration	(6.4)%	(7.3)%	— %
Other deferred adjustments	1.9 %	(0.8)%	0.4 %
Other permanent differences	(9.7)%	— %	— %
Other	4.0 %	(1.8)%	(2.7)%
Effective tax rate	30.4 %	4.2 %	(1.0)%

Our effective tax rate was 30.4% for the year ended December 31, 2023, compared to an effective tax rate of 4.2% for the year ended December 31, 2022 and (1.0)% for the year ended December 31, 2021. The effective tax rates for the periods presented are primarily comprised of U.S. and foreign statutory taxes, excess tax benefits related to stock-based compensation, change in foreign statutory income tax rates, change in fair value of the contingent consideration, change in valuation allowance and other deferred adjustments. The difference in the effective tax rate of 30.4% for the year ended December 31, 2023 as compared to the effective tax rate of 4.2% for the year ended December 31, 2022 was primarily due to Section 162(m) deduction limitations on certain executive compensation, increase in R&D tax credit, and change in valuation allowance during the year ended December 31, 2023.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands) as of:

	December 31,	
	2023	2022
Deferred Tax Assets:		
Stock-based compensation	$ 4,761	$ 4,855
Depreciation and amortization	120	(196)
Operating lease liabilities	6,454	2,169
Net operating loss carryforwards	62,680	76,013
Research and development credit carryforwards	22,690	7,332
Interest expense limitation carryforwards	9,107	5,457
Other	3,904	10,209
Total deferred tax assets	109,716	105,839
Less: valuation allowance	(96,880)	(96,751)
Total net deferred tax assets	$ 12,836	$ 9,088
Deferred Tax Liabilities:		
ROU assets	$ (7,289)	$ (1,464)
Intangible assets	(16,250)	(24,036)
Total deferred tax liabilities	$ (23,539)	$ (25,500)
Net deferred tax liabilities	$ (10,703)	$ (16,412)

At December 31, 2023, the Company had U.S. federal net operating loss (NOL) carryforwards of approximately $218.6 million. Approximately $2.2 million of U.S. federal NOLs will expire in 2037 and remaining U.S. federal NOLs will carryover indefinitely. The Company had U.S. state NOLs of $245.5 million, which will expire between 2033 and 2042. The foreign net operating loss carryforwards have an indefinite carryforward period.

The Company periodically evaluates whether a portion or all of its deferred tax assets will be recovered. The Company records a valuation allowance against deferred tax assets if and to the extent it is more likely than not that they will not be recovered. In evaluating the need for a valuation allowance, the Company weighs all relevant positive and negative evidence, including among other factors, historical financial performance, forecasts of income over the applicable carryforward periods, and the market environment, with each consideration weighted based on its reliability. The Company continues to maintain a full valuation allowance against its otherwise recognizable U.S. deferred income tax assets and a partial valuation allowance on certain foreign deferred tax assets as of December 31, 2023 and 2022. The Company considered all positive and negative historical and prospective evidence in determining its valuation allowance position. The valuation allowance increased by $0.1 million for the year ended December 31, 2023, from $96.8 million to $96.9 million. This increase in the valuation allowance during

the year ended December 31, 2023, was largely attributable to the Radian acquisition and Section 174 capitalization. The Company's NOL carryforwards were generated from domestic and foreign operations.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code), use of the Company's NOL carryforwards may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a rolling three-year period. The Company performed an analysis of changes in ownership for purposes of these Internal Revenue Code sections. Based on the studies performed in 2023, 2022 and 2021, the Company determined that an ownership change did not occur in 2023, 2022 and 2021. Future ownership changes could impact the Company's ability to utilize NOL carryforwards.

The Company has identified unrecognized tax benefits or uncertain tax positions. There has been a liability on uncertain tax positions recorded on the financial statements as of December 31, 2023 and 2022. The Company does not expect that its assessment regarding unrecognized tax benefits and uncertain tax positions will materially change over the following 12 months.

A reconciliation of the beginning and ending balances of unrecognized tax benefits is as follows (in thousands):

Balance at December 31, 2021	$	3,404
Additions based on tax positions related to the current year		574
Deductions for tax positions taken due to settlement		(1,603)
Balance at December 31, 2022		2,375
Additions based on tax positions related to the current year		852
Additions based on tax positions related to the prior year		339
Deductions for tax positions taken due to settlement		(83)
Balance at December 31, 2023	$	3,483

As of December 31, 2023, the total unrecognized tax benefits was $3.5 million. The total amount of unrecognized tax benefit that would affect the effective tax rate was approximately $0.1 million. Due to the time lapse of the indirect ownership change in 2016 whereby losses were utilized in 2017 and 2018, there was a release of uncertain tax positions. There was no interest or penalties to be recognized for the tax year ended December 31, 2023.

The Company has net operating loss and research and development credit carryforwards which may be subject to examination by taxing authorities for tax years beginning with the year ended December 31, 2019. As of December 31, 2023, tax years beginning with the years ended December 31, 2016, December 31, 2017 and December 31, 2018 are no longer subject to examination by the German, French, and the U.K. tax authorities, respectively. The Company is not currently under audit by any taxing authority.

Note 8. Employee Benefit Plan

The Company sponsors a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all U.S. employees who meet minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pre- or post-tax basis. Contributions to the plan by the Company may be made at the discretion of the board of directors. During the years ended December 31, 2023, 2022, and 2021, the Company contributions to the plan amounted to $2.8 million, $2.1 million, and $1.9 million, respectively.

Note 9. Acquisition

On February 25, 2021, the Company acquired all issued and outstanding shares of Contura Limited (Contura) through a Share Purchase Agreement. As a result of the acquisition, the Company acquired a 100% equity interest in Contura.

The Company accounted for the acquisition as a business combination pursuant to ASC 805. In accordance with ASC 805, fair values are assigned to tangible and identifiable intangible assets acquired and liabilities assumed

at the acquisition date based on the information that was available as of the acquisition date. The Company believes that the information available provides a reasonable basis for estimating the fair values of assets acquired and liabilities assumed for the acquisition.

The purchase price consideration for the acquisition totaled $204.7 million, of which $141.4 million was in the form of cash and $55.7 million was in the form of 1,096,583 shares of the Company's common stock. Additionally, a payment of $35 million may be paid to Contura if the Company is able to generate $50 million in Bulkamid sales within a 12-month period before December 31, 2024. As the additional payment is contingent on future sales, an estimate of fair value was initially assessed to be $7.6 million which was considered part of the purchase price consideration and was recorded as other long-term liabilities in the consolidated balance sheet. The cash consideration paid for the acquisition was funded by existing cash on hand.

The following table presents the purchase price allocation of Contura assets acquired and liabilities assumed, based on their estimated fair values as of the February 25, 2021 acquisition date (in thousands):

	Purchase Price Allocation
Assets Acquired	
Cash and cash equivalents	$ 593
Accounts receivable	1,688
Inventory	988
Prepaid expenses and other current assets	115
Property and equipment	52
Other assets	108
Intangible assets	112,200
Total assets acquired	115,744
Liabilities Assumed	
Accounts payable	209
Accrued liabilities	820
Accrued compensation and benefits	315
Operating lease liability	86
Debt	122
Deferred tax liabilities	19,286
Total liabilities assumed	20,838
Net assets acquired	94,906
Purchase price consideration	204,692
Goodwill	$ 109,786

Intangible assets

Identified intangible assets consist of technology, trade names and trademarks, and customer relationships. The fair value of intangible assets and the determination of their respective useful lives were made in accordance with ASC 805 and are outlined in the table below:

	Fair Value (in thousands)	Useful Life
Technology	$ 81,100	12 years
Trade names and trademarks	$ 19,700	Indefinite
Customer relationships	$ 11,400	12 years

Intangible assets were valued using models and approaches best suited for the asset type.

Technology was valued using the Multi-Period Excess Earnings Method (MPEEM), which calculates economic benefits by determining the income attributable to an intangible asset after returns are subtracted for contributory assets. Assumptions in the MPEEM include projected revenue growth rates, future margins, royalty rate indication, and tax rate.

Trade names and trademarks were valued using the Relief from Royalty Method. The relief from royalty method is a variant of the discounted cash flow method, which is a form of the income approach. It is based on the premise that ownership of the intangible asset relieves the need to pay a licensing fee for the ability to use the asset. Assumptions include a discount rate, tax rate, royalty rate indication, long-term growth rate, and implied profit split time period.

Customer relationships were valued using the distributor method. The distributor method was utilized as the asset was determined to be a secondary intangible asset and the Company's product could be sold through distributors. Assumptions used in the distributor method include projected revenue growth rates, future margins, rate of customer retention, and an appropriate discount rate.

Goodwill

Goodwill is calculated as the excess of the consideration transferred over the fair value of the identifiable net assets acquired in a business combination and represents the future economic benefits expected to arise from anticipated synergies and intangible assets acquired that do not qualify for separate recognition, including an assembled workforce, noncontractual relationships, and other agreements. As an indefinite-lived asset, goodwill is not amortized but rather is subject to impairment testing on at least an annual basis. The Contura acquisition resulted in the recognition of $109.8 million of goodwill, which is not deductible for tax purposes.

Contingent consideration

As part of the transaction, the Company agreed to pay Contura $35 million if Bulkamid sales achieve $50 million in any 12-month period before December 31, 2024. The fair value of the estimated contingent consideration was determined by using a binary option-based approach. Inputs used in the assessment include the Company's projected revenue rate, an appropriate discount rate, volatility, and risk-free rate. The estimated fair value of the contingent consideration was preliminarily determined to be $6.8 million. After the March 31, 2021 interim financial statements were issued, the Company received a final valuation report from a third-party valuation firm relating to the contingent consideration. After considering the results of that valuation report, the Company estimated the fair value of the contingent consideration to be $7.6 million as of the acquisition date. As a result, the fair value of the contingent consideration increased by $0.8 million with a corresponding increase to goodwill.

To the extent that the forecast Milestone achievements probabilities changed, future fair value measurement adjustments to the contingent consideration liability will be recognized in the consolidated statements of comprehensive income (loss).

At March 31, 2023, the Milestone was met and $35 million payment was made during the year ended December 31, 2023. The fair value of contingent consideration of $32.6 million is reflected in other current liabilities on the Company's consolidated balance sheet at December 31, 2022.

Deferred tax liabilities

The Company determined the fair value of the deferred tax liabilities related to the acquisition to be $19.3 million.

Transaction-related costs

Acquisition costs are not included as components of consideration transferred and instead are accounted for as expenses in the period in which the costs are incurred. The Company incurred $4.4 million of acquisition-related costs in the first quarter of fiscal year 2021.

Pro forma (Unaudited)

The following unaudited pro forma financial information presents the consolidated results of operations of the Company with Contura for the year ended December 31, 2021, as if the acquisition had occurred on January 1, 2020 instead of February 25, 2021 (in thousands, except share and per share data). Contura's revenue and net loss for the year ended December 31, 2021 were $24.1 million and $2.8 million, respectively, of which $22.7 million in revenue and $2.2 million in net income was recognized after the February 25, 2021 acquisition date. Revenue and net income recognized after the acquisition date were recorded within the Company's consolidated statements of comprehensive income (loss). The pro forma information does not necessarily reflect the results of operations that would have occurred had the entities been a single company during the year ended December 31, 2021.

Net revenue	$	181,643
Net loss	$	(77,535)
Net loss per share, basic and diluted	$	(1.79)
Weighted-average shares used to compute basic and diluted net loss per share		43,237,536

The unaudited pro forma financial information above reflects the following pro forma adjustments:

- An adjustment to decrease net loss for the year ended December 31, 2021 by $4.4 million to eliminate integration and acquisition related costs incurred by the Company and Contura.
- An adjustment to increase net loss for the year ended December 31, 2021 by $1.3 million to reflect amortization of the fair value adjustments for intangible assets as if the assets were acquired January 1, 2020.

Note 10. Subsequent Events

On January 8, 2024, the Company entered into an Agreement and Plan of Merger (the Merger Agreement) with Boston Scientific Corporation, a Delaware corporation (Boston Scientific), and Sadie Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Boston Scientific (Merger Sub), providing for the merger of Merger Sub with and into the Company (the Merger), with the Company surviving the Merger as a wholly owned subsidiary of Boston Scientific. The consummation of the Merger is subject to certain closing conditions, including, among others, the approval of the Company's stockholders of the adoption of the Merger Agreement, the expiration or termination of any waiting periods (and any extension thereof) applicable to the consummation of the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any agreement with a governmental authority not to consummate the Merger, and receipt of certain additional consents, approvals, non-disapprovals and other authorizations of certain other governmental bodies applicable to the Merger. If the Merger is consummated, at the effective time of the Merger (the Effective Time), each share of common stock, par value $0.0001 per share, of the Company issued and outstanding immediately prior to the Effective Time (each, a Share and collectively, the Shares), other than Shares (i) held in the treasury of the Company or owned by any direct or indirect wholly owned subsidiary of the Company, (ii) owned by Merger Sub, Boston Scientific or any direct or indirect wholly owned subsidiary of Boston Scientific or (iii) held by holders who are entitled to and have properly exercised and not waived, withdrawn, failed to perfect or otherwise lost their appraisal rights., will be automatically canceled and converted into the right to receive $71.00 in cash, without interest.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on effectiveness of controls and procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of December 31, 2023, the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2023 due to the material weaknesses in internal control over financial reporting, as described below.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has conducted, with the participation of our Chief Executive Officer and our Chief Financial Officer, an assessment, including testing of the effectiveness, of our internal control over financial reporting as of December 31, 2023. Management's assessment of internal control over financial reporting was conducted using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework (2013 Framework). Based on its assessment, management has concluded that our internal control over financial reporting was not effective as of December 31, 2023 due to material weaknesses in our internal control over financial reporting described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Management's assessment of the Company's internal control over financial reporting as of December 31, 2023 determined that the following material weaknesses exist:

- We did not maintain effective information technology general controls, specifically in the area of access including provisioning, user access reviews and restricted access which could lead to downstream segregation of duties issues related to certain information technology systems that support the Company's financial reporting process, and manual controls impacting substantially all financial statement areas as well as the financial close and reporting process and preparation of financial statements and related disclosures that are dependent upon the information technology systems including evaluation and determination whether components of internal control were present and functioning.
- We did not design and maintain control activities related to the accounting and disclosure related to significant financial statement areas including the accounting for tenant improvements related to leases, allocation of overhead to inventory, and the accounting and disclosure related to income taxes.

These control deficiencies create a reasonable possibility that a material misstatement to the consolidated financial statements will not be prevented or detected on a timely basis, and therefore, we concluded that the deficiencies represent material weaknesses in our internal control over financial reporting, and our internal control over financial reporting was not effective as of December 31, 2023.

Notwithstanding such material weaknesses in internal control over financial reporting, our management, including our Chief Executive Officer and our Chief Financial Officer, has concluded that our consolidated financial statements present fairly, in all material respects, our financial position, results of our operations and our cash flows for the periods presented in this Form 10-K, in conformity with GAAP.

BDO USA, P.C., an independent registered public accounting firm, who audited the consolidated financial statements included in this annual report, has expressed an adverse opinion on the operating effectiveness of the Company's internal control over financial reporting as of December 31, 2023. BDO USA, P.C.'s report appears below.

Remediation Plan

We have identified steps as further described below, to remediate the material weaknesses described in this Item 9A and to enhance our overall control environment. We are committed to ensuring that our internal controls over financial reporting are designed and operating effectively. Our remediation process includes, but is not limited to:

- Enhancing the controls around user access provisioning and monitoring controls to enforce appropriate system access and segregation of duties for systems supporting the Company's internal controls processes and financial reporting;
- Enhancing and designing controls that address the completeness and accuracy of underlying data used in the performance of certain manual controls over accounting transactions;
- Implementing an accounting and disclosure checklist that includes specific review attributes to ensure sufficient evidence of an effective review is documented and maintained to support management's conclusions related to significant financial statement areas; and
- Expanding personnel with appropriate experience to devote sufficient time and resources to our internal controls over accounting and disclosure related to significant financial statement areas.

We believe that these actions will remediate the material weaknesses. The weaknesses will not be considered remediated, however, until the applicable controls operate and management has concluded, through testing, that these controls are operating effectively.

As we continue to evaluate and test the remediation plan outlined above, we may also identify additional measures to address the material weaknesses or modify certain of the remediation procedures described above. Management, with the oversight of the Audit Committee, will continue to take steps necessary to remedy the material weaknesses to reinforce the overall design and capability of our control environment.

Changes in internal control over financial reporting

We made the following material changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal year ended December 31, 2023 to remediate previously reported material weaknesses in our internal control relating to determining the fair value of contingent consideration liability:

- Enhanced and implemented new controls focused on documenting the precision of the management review relating to key methodologies, assumptions and inputs used in the determination of the fair value of contingent consideration liability; and
- Implemented a valuation review checklist that includes specific review attributes to ensure sufficient evidence of an effective review is documented and maintained to support management's conclusions.

Other than the controls implemented to remediate the material weaknesses described above, and the changes in connection with our implementation of the remediation plan for the new material weaknesses discussed above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the most recent fiscal quarter covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Axonics, Inc.
Irvine, California

Opinion on Internal Control over Financial Reporting

We have audited Axonics, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements") and our report dated February 28, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Material weaknesses regarding management's failure to design and maintain effective controls over (i) information technology general controls, specifically in the area of access including provisioning, user access reviews and restricted access which could lead to downstream segregation of duties issues related to certain information technology systems that support the Company's financial reporting process, and manual controls impacting substantially all financial statement areas as well as the financial close and reporting process and preparation of financial statements and related disclosures that are dependent upon the information technology systems including evaluation and determination whether components of internal control were present and functioning, and (ii) the accounting and disclosure related to significant financial statement areas including the accounting for tenant improvements related to leases, allocation of overhead to inventory, and the accounting and disclosure related to income taxes. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2023 consolidated financial statements, and this report does not affect our report dated February 28, 2024 on those consolidated financial statements.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting

includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, P.C.
Costa Mesa, California
February 28, 2024

Item 9B. Other Information.

The Company has an Insider Trading Policy governing the purchase, sale and other dispositions of its securities by directors, officers and employees that is reasonably designed to promote compliance with insider trading laws, rules and regulations and NYSE listing standards. The Insider Trading Policy is filed with this Form 10-K as Exhibit 19.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2023 and delivered to stockholders in connection with our 2024 annual meeting of stockholders.

Item 11. Executive Compensation.

The information required by this Item 11 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2023 and delivered to stockholders in connection with our 2024 annual meeting of stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2023 and delivered to stockholders in connection with our 2024 annual meeting of stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2023 and delivered to stockholders in connection with our 2024 annual meeting of stockholders.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2023 and delivered to stockholders in connection with our 2024 annual meeting of stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements:

The following financial statements are filed as a part of this Annual Report on Form 10-K:

Report of Independent Registered Public Accounting Firm (BDO USA, P.C.; Costa Mesa, California; PCAOB ID#243)

Consolidated Balance Sheets

Consolidated Statements of Comprehensive Income (Loss)

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

2. Financial Statement Schedules:

All schedules are omitted because they are not applicable or the amounts are immaterial or the required information is presented in the consolidated financial statements and notes thereto in Part II, Item 8 above.

3. Exhibits:

EXHIBIT INDEX

Exhibit Number	Exhibit Title	Incorporated by Reference				Filed Herewith (X)
		Form	File No.	Exhibit	Filing Date	
2.1^	Agreement and Plan of Merger, dated as of January 8, 2024, among Boston Scientific Corporation, Sadie Merger Sub, Inc. and Axonics, Inc.	8-K	001-38721	2.1	1/8/2024	
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-38721	3.1	11/5/2018	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Registrant filed April 1, 2021.	8-K	001-38721	3.1	4/1/2021	
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation, dated May 31, 2022.	8-K	001-38721	3.1	6/1/2022	
3.4	Amended and Restated Bylaws.	8-K	001-38721	3.2	11/5/2018	
3.5	Certificate of Amendment to Amended and Restated Bylaws, dated May 31, 2022.	8-K	001-38721	3.2	6/1/2022	
4.1	Specimen certificate evidencing shares of common stock of the Registrant.	S-1	333-227732	4.1	10/5/2018	
4.2	Description of Securities.	10-K	001-38721	4.4	3/1/2021	
10.1+	2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.8	10/22/2018	
10.2+	First Amendment to the Axonics, Inc. 2018 Omnibus Incentive Plan.	8-K	001-38721	10.1	6/1/2022	
10.3+	Form of Option Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.9	10/22/2018	
10.4+	Form of Restricted Shares Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.10	10/22/2018	
10.5+	Form of RSU Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.11	10/22/2018	
10.6	Loan and Security Agreement, dated February 6, 2018, by and between Silicon Valley Bank.	S-1	333-227732	10.16	10/5/2018	
10.7	Amendment to Loan and Security Agreement, dated October 22, 2018, by and between Silicon Valley Bank and the Registrant.	S-1/A	333-227732	10.31	10/22/2018	

10.8	Second Amendment to Loan and Security Agreement, dated as of December 30, 2019, by and between Axonics Modulation Technologies, Inc. and Silicon Valley Bank.	8-K	001-38721	1.1	1/2/2020	
10.9	Loan and Security Agreement, dated as of February 25, 2021, by and among Silicon Valley Bank and Axonics, Inc.	10-Q	001-38721	10.3	5/7/2021	
10.10	Lease, dated November 30, 2017, by and between The Irvine Company LLC and the Registrant.	S-1	333-227732	10.13	10/5/2018	
10.11	First Amendment to Lease, dated April 12, 2018, by and between The Irvine Company LLC and the Registrant.	S-1	333-227732	10.14	10/5/2018	
10.12	Second Amendment to Lease, dated July 11, 2018, by and between The Irvine Company LLC and the Registrant.	S-1	333-227732	10.15	10/5/2018	
10.13	Third Amendment to Lease, dated June 28, 2019, by and between The Irvine Company LLC and Axonics Modulation Technologies, Inc.	8-K	001-38721	10.1	7/12/2019	
10.14	Lease, dated April 1, 2023, between Sand Canyon Business Center I LLC and Axonics, Inc.	8-K	001-38721	10.1	4/6/2023	
10.15	Third Amendment to Lease, dated April 1, 2023, between The Irvine Company LLC and Axonics, Inc.	8-K	001-38721	10.2	4/6/2023	
10.16+	Executive Employment Agreement, dated October 2, 2023, by and between the Company and Raymond W. Cohen.	8-K	001-38721	10.2	10/4/2023	
10.17+	Executive Employment Agreement, dated June 5, 2019, by and between Dan L. Dearen and the Registrant.	10-Q	001-38721	10.4	8/5/2019	
10.18+	Executive Employment Agreement, dated June 5, 2019, by and between Rinda Sama and the Registrant.	10-Q	001-38721	10.4	8/5/2019	
10.19+	Executive Employment Agreement, dated October 2, 2023, by and between the Company and Kari Keese.	8-K	001-38721	10.1	10/4/2023	
10.20+	Amendment to Executive Employment Agreement, dated November 1, 2023, by and between Rinda Sama and the Registrant.					X

10.21+	Amendment to Executive Employment Agreement, dated November 1, 2023, by and between John Woock, Ph.D. and the Registrant.					X
10.22+	Amendment to Executive Employment Agreement, dated November 1, 2023, by and between Alfred Ford Jr. and the Registrant.					X
10.23+	Summary of 2024 Special Cash Bonus Incentive Plan					X
10.24	License Agreement, dated October 1, 2013, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.	S-1	333-227732	10.1	10/5/2018	
10.25	First Amendment to License Agreement, dated February 19, 2014, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.	S-1	333-227732	10.2	10/5/2018	
10.26	Second Amendment to License Agreement, dated February 25, 2014, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.	S-1	333-227732	10.3	10/5/2018	
10.27	Side Letter, dated October 1, 2013, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.	S-1	333-227732	10.4	10/5/2018	
10.28*	Form of Indemnification Agreement by and between the Registrant and its directors and officers.	S-1/A	333-227732	10.12	10/22/2018	
10.29*	Agreement, dated February 25, 2021, by and among Axonics, Inc., Axonics Modulation Technologies, U.K. Limited and Contura Holdings.	10-Q	001-38721	10.1	5/7/2021	
10.3	Exclusive Manufacturing and Supply Agreement, dated February 25, 2021, by and between Contura International A/S and Contura Limited.	10-Q	001-38721	10.2	5/7/2021	
21.1	List of Subsidiaries.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (see page 124)					X

31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.	X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.	X
32.1#	Certifications of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
32.2#	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
97	Incentive-based Compensation Recovery Policy	X
101.INS**	XBRL Instance Document.	X
101.SCH**	XBRL Taxonomy Extension Schema Document.	X
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.	X

\+ Indicates management contract or compensatory plan.

\# The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Annual Report on Form 10-K), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

* Portions of this exhibit have been omitted as the Company has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm if publicly disclosed.

** In accordance with Rule 402 of Regulation S-T, this interactive data file is deemed not filed or part of this Annual Report on Form 10-K for purposes of Sections 11 or 12 of the Securities Act or Section 18 of the Exchange Act and otherwise is not subject to liability under these sections.

^ Schedules to this Exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K under the Securities Act of 1933, as amended. A copy of any omitted schedule will be furnished to the SEC upon request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AXONICS, INC.

Date: February 28, 2024

By: /s/ Raymond W. Cohen
Raymond W. Cohen
Chief Executive Officer and Director

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Raymond W. Cohen and Kari L. Keese as his attorney-in-fact, with full power of substitution, for him in any and all capacities, to sign any amendments to this Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each attorney-in-fact, or his substitute, may do or case to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, the report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: February 28, 2024	By:	/s/ Raymond W. Cohen Raymond W. Cohen Chief Executive Officer and Director (Principal Executive Officer)
Date: February 28, 2024	By:	/s/ Kari L. Keese Kari L. Keese Chief Financial Officer (Principal Financial and Accounting Officer)
Date: February 28, 2024	By:	/s/ Michael H. Carrel Michael H. Carrel Chairman of the Board and Director
Date: February 28, 2024	By:	/s/ Jane E. Kiernan Jane E. Kiernan Director
Date: February 28, 2024	By:	/s/ Robert E. McNamara Robert E. McNamara Director
Date: February 28, 2024	By:	/s/ Nancy Snyderman, M.D., FACS Nancy Snyderman, M.D., FACS Director
Date: February 28, 2024	By:	/s/ David M. Demski David M. Demski Director
Date: February 28, 2024	By:	/s/ Esteban López Esteban López, M.D. Director

Exhibit 10.20

AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

This Amendment to the Executive Employment Agreement (this "Amendment") is dated as of November 1, 2023 by and between Axonics, Inc., a Delaware corporation (the "Company"), and Rinda Sama ("Executive").

WHEREAS, Executive currently serves as Chief Operating Officer of the Company pursuant to an Executive Employment Agreement dated June 5, 2019, with a Term scheduled to end on June 4, 2024 (the "Agreement").

WHEREAS, the Company and Executive desire to continue Executive's employment with the Company and wish to amend the terms of the Agreement.

NOW, THEREFORE, in consideration of the premises and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **EXTENSION OF TERM**. The Term of the Agreement is hereby extended for three (3) additional years and shall end on June 4, 2027, unless earlier terminated pursuant to Section 5 of the Agreement (the "Extended Term").
2. **CONTINUATION IN FORCE OF EMPLOYMENT AGREEMENT**. Other than as specifically amended hereby, the terms and conditions of the Agreement shall remain in full force and effect during the Extended Term.

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first above written.

COMPANY:

Axonics, Inc.

By: /s/ Raymond W. Cohen

Raymond W. Cohen

CEO

EXECUTIVE:

By: /s/ Rinda Sama

Rinda Sama

Exhibit 10.21

AMENDMENT TO AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Amendment to the Amended and Restated Executive Employment Agreement (this "Amendment") is dated as of November 1, 2023 by and between Axonics, Inc., a Delaware corporation (the "Company"), and John Woock, Ph.D. ("Executive").

WHEREAS, Executive currently serves as Executive Vice President, Chief Marketing & Strategy Officer of the Company pursuant to an Amended and Restated Executive Employment Agreement dated June 6, 2019, with a Term scheduled to end on June 5, 2024 (the "Agreement").

WHEREAS, the Company and Executive desire to continue Executive's employment with the Company and wish to amend the terms of the Agreement.

NOW, THEREFORE, in consideration of the premises and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **EXTENSION OF TERM**. The Term of the Agreement is hereby extended for three (3) additional years and shall end on June 5, 2027, unless earlier terminated pursuant to Section 5 of the Agreement (the "Extended Term").
2. **TERMINATION OF EMPLOYMENT**. Section 7(b)(i) shall be replaced in its entirety by the following:

"Executive shall receive cash severance in an amount equal to one (1) year of Base Salary as in effect on the Termination Date. Such payment shall be made in a single cash payment on the Cash Severance Commencement Date."

1. **CONTINUATION IN FORCE OF EMPLOYMENT AGREEMENT**. Other than as specifically amended hereby, the terms and conditions of the Agreement shall remain in full force and effect during the Extended Term.

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first above written.

COMPANY:

Axonics, Inc.

By: /s/ Raymond W. Cohen

Raymond W. Cohen

CEO

EXECUTIVE:

By: /s/ John Woock, Ph.D.

John Woock, Ph.D.

Exhibit 10.22

AMENDMENT TO AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Amendment to the Amended and Restated Executive Employment Agreement (this "Amendment") is dated as of November 1, 2023 by and between Axonics, Inc., a Delaware corporation (the "Company"), and Alfred Ford Jr. ("Executive").

WHEREAS, Executive currently serves as Chief Commercial Officer of the Company pursuant to an Amended and Restated Executive Employment Agreement dated June 5, 2019, with a Term scheduled to end on June 4, 2024 (the "Agreement").

WHEREAS, the Company and Executive desire to continue Executive's employment with the Company and wish to amend the terms of the Agreement.

NOW, THEREFORE, in consideration of the premises and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **EXTENSION OF TERM**. The Term of the Agreement is hereby extended for three (3) additional years and shall end on June 4, 2027, unless earlier terminated pursuant to Section 5 of the Agreement (the "Extended Term").
2. **TERMINATION OF EMPLOYMENT**. Section 7(b)(i) shall be replaced in its entirety by the following:

"Executive shall receive cash severance in an amount equal to one (1) year of Base Salary as in effect on the Termination Date. Such payment shall be made in a single cash payment on the Cash Severance Commencement Date."

1. **CONTINUATION IN FORCE OF EMPLOYMENT AGREEMENT**. Other than as specifically amended hereby, the terms and conditions of the Agreement shall remain in full force and effect during the Extended Term.

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement as of the date first above written.

COMPANY:

Axonics, Inc.

By: /s/ Raymond W. Cohen

Raymond W. Cohen

CEO

EXECUTIVE:

By: /s/ Alfred Ford Jr.

Alfred Ford Jr.

Exhibit 10.23

AXONICS, INC.
SUMMARY OF 2024 SPECIAL CASH BONUS INCENTIVE PLAN

On January [XX], 2024, the Board of Directors of Axonics, Inc. ("the Company"), based upon the recommendation of the Compensation Committee of the Board of Directors of the Company, approved a special cash bonus incentive plan (the "Plan") for the year ending December 31, 2024 for the named executive officers of the Company. The Plan provides for cash bonuses to certain of its executives during the period between January 1, 2024 and the earlier of (a) the Closing date of the merger with Boston Scientific Corporation ("Effective Time") and (b) December 31, 2024. In the event that the Effective Time occurs on a date that is not the last day of a month, the bonus amount for the month in which the Effective Time occurs will be pro-rated (the numerator will be equal to the number of days between the first day of such month and the Effective Time, and the denominator will be equal to the number of days in such month). All payments due under the 2024 Executive Bonus Program shall be made promptly following the Effective Time. Each named executive eligible to participate in the 2024 special cash bonus program and the corresponding monthly bonus amount that such individual may be entitled to receive is listed below.

In order to be eligible to receive a payment under the 2024 Executive Bonus Program, an executive officer must be continuously employed with the Company from January 1, 2024 through the Effective Time; provided, however, if an executive's employment is terminated prior to the Effective Time by the Company without "cause" as defined under such executive's employment agreement or offer letter, as applicable, such executive shall be entitled to receive a pro-rated payment (the numerator will be equal to the number of days between January 1, 2024 and the executive's termination date, and the denominator will be the number of days between January 1, 2024 and the Effective Time). There is no formally adopted plan document for this special bonus.

Title	Monthly Bonus Amount
Chief Executive Officer	$568,444
Chief Operating Officer	$232,969
EVP, Chief Marketing and Strategy Officer	$232,969
Chief Financial Officer	$203,149
Chief Commercial Officer	$203,149
Chief Medical Officer	$173,329

Exhibit 21.1

List of Subsidiaries of
Axonics, Inc.

Name of Subsidiary	Jurisdiction of Incorporation or Organization
Axonics Europe, S.A.S.	France
Axonics Modulation Technologies, U.K. Limited	England and Wales
Axonics Modulation Technologies Australia Pty Ltd	Australia
Axonics Women's Health Limited	England and Wales
Bulkamid SARL	France
Axonics GmbH	Germany
Contura, Inc.	United States

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-234546) and Form S-8 (No.333-228170) of Axonics, Inc. (the "Company") of our reports dated February 28, 2024, relating to the consolidated financial statements and the effectiveness of the Company's internal control over financial reporting, which appear in this Annual Report on Form 10-K. Our report on the effectiveness of the internal control over financial reporting expresses an adverse opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2023.

/s/ BDO USA, P.C.
Costa Mesa, California

February 28, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Raymond W. Cohen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Axonics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2024

By: /s/ Raymond W. Cohen
Raymond W. Cohen
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Kari L. Keese, certify that:

1. I have reviewed this Annual Report on Form 10-K of Axonics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2024

By: /s/ Kari L. Keese
Kari L. Keese
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Axonics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2024

By: /s/ Raymond W. Cohen
Raymond W. Cohen
Chief Executive Officer and Director
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Axonics, Inc. and will be retained by Axonics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Axonics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2024

By: /s/ Kari L. Keese
Kari L. Keese
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Axonics, Inc. and will be retained by Axonics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 97

AXONICS, INC.

INCENTIVE-BASED COMPENSATION RECOVERY POLICY

1. Policy Purpose. The purpose of this Axonics, Inc. (the "Company") Incentive-Based Compensation Recovery Policy (this "Policy") is to enable the Company to recover Erroneously Awarded Compensation in the event that the Company is required to prepare an Accounting Restatement. This Policy is intended to comply with the requirements set forth in Listing Rule 5608 of the corporate governance rules of The NASDAQ Stock Market (the "Listing Rule") and shall be construed and interpreted in accordance with such intent. Unless otherwise defined in this Policy, capitalized terms shall have the meaning ascribed to such terms in Section 7. This Policy shall become effective on December 1, 2023. Where the context requires, reference to the Company shall include the Company's subsidiaries and affiliates (as determined by the Committee in its discretion).

2. Policy Administration. This Policy shall be administered by the Compensation Committee of the Board (the "Committee") unless the Board determines to administer this Policy itself. The Committee has full and final authority to make all determinations under this Policy. All determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company, its affiliates, its stockholders and Executive Officers. Any action or inaction by the Committee with respect to an Executive Officer under this Policy in no way limits the Committee's actions or decisions not to act with respect to any other Executive Officer under this Policy or under any similar policy, agreement or arrangement, nor shall any such action or inaction serve as a waiver of any rights the Company may have against any Executive Officer other than as set forth in this Policy.

3. Policy Application. This Policy applies to all Incentive-Based Compensation received by a person: (a) after October 2, 2023, and beginning service as an Executive Officer; (b) who served as an Executive Officer at any time during the performance period for such Incentive-Based Compensation; (c) while the Company had a class of securities listed on a national securities exchange or a national securities association; and (d) during the three completed fiscal years immediately preceding the Accounting Restatement Date. In addition to such last three completed fiscal years, the immediately preceding clause (d) includes any transition period that results from a change in the Company's fiscal year within or immediately following such three completed fiscal years; provided, however, that a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to twelve months shall be deemed a completed fiscal year. For purposes of this Section 3, Incentive-Based Compensation is deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period. For the avoidance of doubt, Incentive-Based Compensation that is subject to both a Financial Reporting Measure vesting condition and a service-based vesting condition shall be considered received when the relevant Financial Reporting Measure is achieved, even if the Incentive-Based Compensation continues to be subject to the service-based vesting condition.

4. Policy Recovery Requirement. In the event of an Accounting Restatement, the Company must recover, reasonably promptly, Erroneously Awarded Compensation, in amounts determined pursuant to this Policy. The Company's obligation to recover Erroneously Awarded Compensation is not dependent on if or when the Company files restated financial statements. Recovery under this Policy with respect to an Executive Officer shall not require the finding of any misconduct by such Executive Officer or such Executive Officer being found responsible for the accounting error leading to an Accounting Restatement. In the event of an Accounting Restatement, the Company shall satisfy the Company's obligations under this Policy to recover any amount owed from any applicable Executive Officer by exercising its sole and absolute discretion in how to accomplish such recovery. The Company's recovery obligation pursuant to this Section 4 shall not apply to the extent that the Committee, or in the absence of the Committee, a majority of the independent directors serving on the Board, determines that such recovery would be impracticable and:

    a. The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company must make a reasonable attempt to recover such Erroneously Awarded Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Stock Exchange; or

b. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the registrant, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Code.

5. Policy Prohibition on Indemnification and Insurance Reimbursement. The Company is prohibited from indemnifying any Executive Officer or former Executive Officer against the loss of Erroneously Awarded Compensation. Further, the Company is prohibited from paying or reimbursing an Executive Officer for purchasing insurance to cover any such loss.

6. Required Policy-Related Filings. The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the Federal securities laws, including disclosures required by U.S. Securities and Exchange Commission filings.

7. Definitions.

a. "Accounting Restatement" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

b. "Accounting Restatement Date" means the earlier to occur of: (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if the Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; and (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

c. "Board" means the board of directors of the Company.

d. "Code" means the U.S. Internal Revenue Code of 1986, as amended. Any reference to a section of the Code or regulation thereunder includes such section or regulation, any valid regulation or other official guidance promulgated under such section, and any comparable provision of any future legislation or regulation amending, supplementing, or superseding such section or regulation.

e. "Erroneously Awarded Compensation" means, in the event of an Accounting Restatement, the amount of Incentive-Based Compensation previously received that exceeds the amount of Incentive-Based Compensation that otherwise would have been received had it been determined based on the restated amounts in such Accounting Restatement, and must be computed without regard to any taxes incurred or paid by the relevant Executive Officer; provided, however, that for Incentive-Based Compensation based on stock price or total stockholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement: (i) the amount of Erroneously Awarded Compensation must be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total stockholder return upon which the Incentive-Based Compensation was received; and (ii) the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the Stock Exchange.

f. "Executive Officer" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice- president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. An executive officer of the Company's parent or subsidiary is deemed an "Executive Officer" if the executive officer performs such policy making functions for the Company. For the avoidance of doubt, "Executive Officer" includes, but is not limited to, any person identified as an executive officer pursuant to Item 401(b) of Regulation S-K under the U.S. Securities Act of 1933, as amended.

g. "Financial Reporting Measure" means any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measure; provided, however, that a Financial Reporting Measure is not required to be presented within the Company's financial statements or

included in a filing with the U.S. Securities and Exchange Commission to qualify as a "Financial Reporting Measure." For purposes of this Policy, "Financial Reporting Measure" includes, but is not limited to, stock price and total stockholder return.

h. "Incentive-Based Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

i. "Stock Exchange" means the national stock exchange on which the Company's common stock is listed.

8. Acknowledgement. Each Executive Officer shall sign and return to the Company, within 30 calendar days following the later of (i) the effective date of this Policy first set forth above or (ii) the date the individual becomes an Executive Officer, the Acknowledgement Form attached hereto as Exhibit A, pursuant to which the Executive Officer agrees to be bound by, and to comply with, the terms and conditions of this Policy.

9. Committee Indemnification. Any members of the Committee, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

10. Severability. The provisions in this Policy are intended to be applied to the fullest extent of the law. To the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision shall be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

11. Amendment; Termination. The Board may amend this Policy from time to time in its sole and absolute discretion and shall amend this Policy as it deems necessary to reflect the Listing Rule. The Board may terminate this Policy at any time.

12. Other Recovery Obligations; General Rights. To the extent that the application of this Policy would provide for recovery of Incentive-Based Compensation that the Company recovers pursuant to Section 304 of the Sarbanes-Oxley Act or other recovery obligations, the amount the relevant Executive Officer has already reimbursed the Company will be credited to the required recovery under this Policy. This Policy shall not limit the rights of the Company to take any other actions or pursue other remedies that the Company may deem appropriate under the circumstances and under applicable law. To the maximum extent permitted under the Listing Rule, this Policy shall be administered in compliance with (or pursuant to an exemption from the application of) Section 409A of the Code.

13. Successors. This Policy is binding and enforceable against all Executive Officers and their beneficiaries, heirs, executors, administrators or other legal representatives.

14. Governing Law; Venue. This Policy and all rights and obligations hereunder are governed by and construed in accordance with the internal laws of the State of Delaware, excluding any choice of law rules or principles that may direct the application of the laws of another jurisdiction. All actions arising out of or relating to this Policy shall be heard and determined exclusively in the Court of Chancery of the State of Delaware or, if such court declines to exercise jurisdiction or if subject matter jurisdiction over the matter that is the subject of any such legal action or proceeding is vested exclusively in the U.S. Federal courts, the U.S. District Court for the District of Delaware.

EXHIBIT A

AXONICS, INC.

INCENTIVE-BASED COMPENSATION RECOVERY POLICY ACKNOWLEDGEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Axonics, Inc. (the "Company") Incentive-Based Compensation Recovery Policy (the "Policy").

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously Awarded Compensation (as defined in the Policy) to the Company to the extent required by, and in a manner consistent with, the Policy. Further, by signing below, the undersigned agrees that the terms of the Policy shall govern in the event of any inconsistency between the Policy and the terms of any employment agreement to which the undersigned is a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid.

EXECUTIVE OFF

_____

Signature

_____

Print Name

_____

Date