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, 2018
or
o **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 Modulation Technologies, 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)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o 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 o 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 o
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 o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒
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	o	Accelerated filer	o
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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☒
The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter, and therefore cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.
As of March 1, 2019, 27,840,916 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, 2018. 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.

TABLE OF CONTENTS

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:

- announcements of regulatory approval or disapproval of our proprietary rechargeable sacral neuromodulation ("SNM") system ("r-SNM System") and any future enhancements to our r-SNM System;
- adverse results from or delays in clinical studies of our r-SNM System;
- unanticipated safety concerns related to the use of our r-SNM System;
- U.S. Food and Drug Administration ("FDA") or other U.S. or foreign regulatory or legal actions or changes affecting us or our industry;
- any termination or loss of intellectual property rights;
- 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;
- 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 r-SNM System;
- 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;
- 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;
- additions or departures of key personnel;
- 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;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- the results of any future legal proceedings.

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,” “our company,” “we,” “us” and “our” refer to Axonics Modulation Technologies, Inc. and our consolidated subsidiaries.

This Annual Report on Form 10-K includes our trademarks and trade names, including, without limitation, r-SNM® and Axonics SNM System®, 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 medical technology company that has developed and is commercializing an innovative and minimally invasive implantable neurostimulation system. SNM therapy is primarily used to treat patients with overactive bladder ("OAB"), including urinary urgency incontinence ("UUI") and urinary urgency frequency ("UUF"), fecal incontinence ("FI"), and urinary retention ("UR").

Our proprietary r-SNM System delivers mild electrical pulses to the targeted sacral nerve in order to restore normal communication to and from the brain to reduce the symptoms of urinary and fecal dysfunction. We believe our proprietary r-SNM System offers significant advantages, including being the first and only rechargeable SNM system that is designed to last approximately 15 years and be 60% smaller than the InterStim II System ("InterStim II"), which is the only existing competitive SNM product and is marketed by Medtronic plc ("Medtronic"). We currently have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR. On December 3, 2018, we submitted a literature-based pre-market approval ("PMA") application to the FDA for OAB and UR. This literature-based PMA was based on reasonable safety and effectiveness data from a literature review. In this PMA filing, we submitted existing literature reporting on InterStim II. In addition to the technical specifications, testing data and published literature, we included one-year follow-up data from our 51-patient RELAX-OAB European post-market clinical follow-up study to support the PMA, and subsequently provided the FDA with the clinical results on the first 60 patients to reach their six-month primary endpoint from our ARTISAN-SNM pivotal study. Since the original PMA submission in December 2018, we have submitted various amendments to the PMA. These amendments include data in support of conditional full-body magnetic resonance imaging ("MRI") labeling and complete three-month and six-month clinical data from the ARTISAN-SNM study. On March 1, 2019, we submitted a new literature-based PMA seeking approval for FI. This PMA is also based on an existing literature review of Interstim II. Typically, the PMA review process takes six to 18 months, with the duration depending on a variety of factors. We believe our r-SNM System has the potential to disrupt and grow the estimated $650 million global SNM market in 2018, which is currently controlled by Medtronic as a single participant.

We are continuing to develop a growing body of compelling clinical evidence that demonstrates the safety, effectiveness, and sustained benefits of our r-SNM System. We have in process two clinical studies relating to our r-SNM System; a European study, RELAX-OAB, and a U.S. pivotal study, ARTISAN-SNM. In our clinical work to date, we have implanted 180 patients, and in our investigator-initiated case series and through our commercial efforts in Europe and Canada, we have implanted approximately 100 additional patients. In June 2018, we completed the enrollment and implantation of 129 patients with UUI for our ARTISAN-SNM pivotal study. These patients are being evaluated at 14 centers in the United States and five in Europe. We determined the study's primary endpoint to be the percentage of patients that had a therapeutic response, defined as at least a 50% reduction in the number of UUI episodes per day on a three-day bladder diary at six months post-implant.

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

- The study has passed the six-month primary endpoint;
- At six months, 116 of the 129 implanted patients, or 90%, were therapy responders, and the study has met all additional primary and secondary efficacy endpoints;
- At six months, 93% of all implanted patients reported being "very" or "moderately" satisfied with the therapy;
- No serious device-related adverse events have been reported; and
- We submitted the complete six-month results of the study to the FDA as an amendment to our previously submitted literature-based PMA, and intend to follow patients out to two years.

Our European RELAX-OAB study that began in June 2016 evaluated 51 patients at seven sites in Europe that suffered from OAB subtypes UUI and/or UUF. The 12-month results were published in the peer-reviewed *Journal of Neurourology and Urodynamics* in January 2019.

All patients were directly implanted and evaluated to determine if they were test 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, within one month. 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 are as follows:

- The study has completed one-year follow-ups and will complete two-year follow-ups in the second quarter of 2019;
- Therapy responder rate at 12 months for the 43 patients who continued with study follow-up was 94% for test responders and 72% for all implanted patients; and
- No serious device-related adverse events have been reported.

OAB and FI are dysfunctions, rather than diseases, with a complex group of symptoms that frequently overlap and may be caused by a diverse set of underlying conditions. These dysfunctions affect individuals of both sexes and all ages. OAB causes a sudden urge to urinate that may be difficult to stop, and could lead to the involuntary leakage of urine. In the United States and Europe, based on phone-based surveys as published in clinical literature, an estimated 87 million adults suffer from OAB. Additionally, we estimate that 40 million adults suffer from FI in the United States and Europe. The primary types of urinary and fecal dysfunction are as follows:

- UUI is the sudden need to urinate accompanied by involuntary leakage of urine, regardless of frequency;
- UUF is the sudden need to urinate an abnormal number of times, typically more than eight times per day;
- UR is the inability to completely or partially empty the bladder; and
- FI is the inability to control bowel function that could lead to involuntary leakage from the rectum.

Symptoms of urinary and fecal dysfunction can have debilitating impacts on social, occupational, and daily activities, which can lead to loss of self-confidence, depression, anxiety, and decreased sexual function and marital satisfaction. Comorbidities, which are generally more prevalent in patients with urinary and fecal dysfunction, may include falls and fractures, urinary tract infections, skin infections, vulvovaginitis, and cardiovascular and central nervous system pathologies. Left untreated, the effects of these dysfunctions impose a significant cost to society and place a high burden on healthcare systems.

We believe that SNM therapy is an effective treatment alternative for urinary and fecal dysfunction patients whose symptoms have not been adequately resolved by first and second line therapies. We believe that approximately two-thirds of patients in the United States with urinary and fecal dysfunction that are treated with SNM therapy have either UUI alone, or UUI in combination with FI or another subtype of OAB. We believe that approximately 85% of the SNM addressable market for OAB consists of female patients. Anatomical and physiological differences in the lower urinary tract of males and females may help to explain these variations.

First-line therapies for OAB include behavioral changes such as diet, exercise, timed voiding, pelvic floor exercises, and biofeedback, all of which often have limited effectiveness. Second-line therapies for OAB consist of drug therapy and medical management, and may be effective; however, the use of medication can cause undesirable side effects and the effectiveness may decrease over time with prolonged use. First- and second-line therapies comprise the largest segment of the treatment market for OAB. Patients who fail, or are contraindicated or refractory for, both first- and second-line therapies may be eligible for SNM as a third-line therapy.

SNM therapy has been commercially available in the United States for over 20 years and has been clinically proven to provide a safe, effective, reversible, and long-lasting solution. According to a study published in the *Journal of Neurourology and Urodynamics*, Siegel et al. in 2014, SNM therapy is the only third-line therapy for OAB that has objectively demonstrated superior efficacy to standard OAB medical therapy. Relative to the other third-line therapies such as onabotulinumtoxinA (“BOTOX”) injections and percutaneous tibial nerve stimulation (“PTNS”), we believe SNM therapy has therapeutic advantages that include better efficacy and patient compliance.

We believe that our r-SNM System offers similar therapeutic benefits and competitive advantages to the only currently available SNM technology, InterStim II. We believe that our r-SNM System is the first and only system for SNM therapy with a rechargeable implantable neurostimulator (“INS”), that is designed to last approximately 15 years.

As a result, patients implanted with our r-SNM System do not need to undergo replacement surgery every three to five years, as is the case for patients implanted with InterStim II, potentially reducing the risks of surgery and associated infections. Our r-SNM System is designed to be full-body MRI scan conditionally safe, which avoids the risk and burden associated with the explant procedure that a patient may be subjected to, should the patient require an MRI scan for body part other than head, which is currently required for patients implanted with InterStim II. This full-body MRI scan conditionally safe feature may allow more patients to choose SNM therapy to treat their urinary and bowel dysfunction. In addition, we believe patients who have historically resisted SNM therapy because of the required multiple surgeries may be more inclined to be treated by our r-SNM System. Further, by reducing the number of replacement surgeries, physicians and facilities can utilize their resources more efficiently. Finally, our technology has the potential to significantly reduce overall costs to the healthcare system. In 2016, we commissioned a study that concluded that a rechargeable SNM system with a 15-year battery life could potentially reduce overall U.S. healthcare costs by up to $12 billion over a 15-year horizon.

We have designed and developed a proprietary method protected by patents, know-how, and trade secrets that enables us to combine ceramic and titanium for the INS enclosure of our r-SNM System. This method enables us to incorporate a significantly smaller battery and recharging coil into our INS, which enables us to provide a smaller sized implant that is half the weight of InterStim II, charges wirelessly and communicates wirelessly with the external components of our r-SNM System. In addition, we engineered the INS to deliver constant-current stimulation, automatically adapting stimulation output to the body’s physiological changes, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. Our r-SNM System also includes an easy-to-use patient remote control. Finally, we designed and custom built a touchscreen clinician programmer that guides the implanting physician through electrode placement and stimulation programming. On February 22, 2019, we received CE Mark approval on our r-SNM System for 1.5T/3.0T MRI full-body conditional labeling. We also submitted to the FDA our testing data to support a full-body MRI labeling on February 12, 2019. We intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System. Our goals include extending the time between recharging sessions to once a month, introducing features that would enable us to connect our INS to an already implanted InterStim II lead, and expanding the suite of product solutions available for SNM therapy over time.

Our r-SNM System consists of several components and accessories that provide a smoothly integrated, long-lasting, intuitive, and easy-to-use system. The miniaturized INS is a five cubic centimeter, rechargeable implantable stimulator designed to provide stimulation through a tined, four-electrode lead. SNM therapy generally consists of two phases, an evaluation period, also called the external trial period, which typically lasts a few days to a few weeks, and a permanent implant for those patients who experience a successful external trial period. The permanent implant procedure typically occurs in a hospital or an outpatient setting and includes implantation of the INS and, if a temporary lead was used for the external trial period, 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. The INS is programmed by, and wirelessly communicates with, the clinician programmer, at a range of up to approximately three-feet. The patient has the ability to adjust stimulation intensity up or down or switch on or off, using a discrete, small and easy-to-use wireless remote control that communicates with the device at a range of up to approximately three-feet. The INS charges wirelessly for approximately one hour once every two weeks under normal use conditions.

The market for SNM therapy is large and growing. We estimate that the current global SNM market was approximately $650 million in 2018, which represents approximately 46,000 patient implants, including 10,000 patients undergoing replacement implants. We believe that nearly 90% of sales in this market are generated in the United States.

We believe our initial target market consists of approximately four million adults in the United States and Europe who suffer from symptoms of either urinary or fecal dysfunction, who have already failed first and second line therapies and are readily treatable with, and eligible candidates for, SNM therapy. Further, we estimate that the global annual addressable SNM market is presently approximately one percent penetrated. We believe this represents a compelling opportunity for our r-SNM System to capture market share and further penetrate and grow the current U.S. market.

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

the process of building a dedicated direct sales organization, which will initially target the estimated 1,000 physician specialists that represent a majority of the implant volume in the United States. We estimate that approximately 80% of U.S. implant volume is generated by these 1,000 physicians. We are in the process of hiring a specialty sales force of approximately 100 sales professionals, regional sales managers and clinical specialists in advance of the anticipated commercial launch of our r-SNM System in the United States. In addition, we plan to expand our current sales team into select international markets.

On October 1, 2013, we entered into a license agreement (the "License Agreement"), with the Alfred E. Mann Foundation for Scientific Research ("AMF"), pursuant to which AMF agreed to license to us certain patents and know-how ("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 (the "AMF Licensed Products").

Our Market

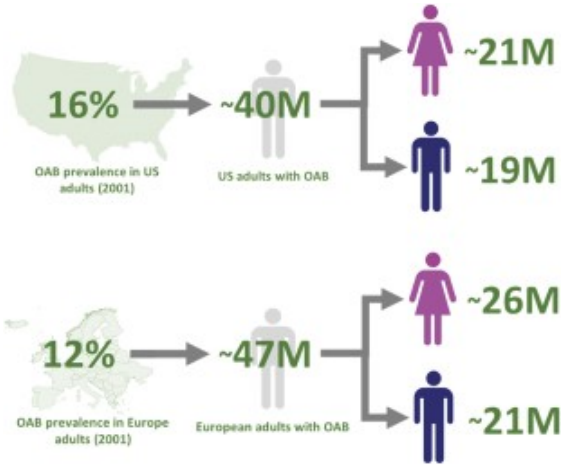
We believe our initial target market consists of approximately four million adults in the United States and Europe who suffer from symptoms of either urinary or fecal dysfunction, who have already failed first and second line therapies and are readily treatable with, and eligible candidates for, SNM therapy. Specifically, we believe this four million adult market consists of approximately three million adults with symptoms of urinary dysfunction and approximately one million adults with symptoms of fecal dysfunction within these regions. While we anticipate expanding into other geographic regions over time, such as Canada and Australia, we will initially focus on the United States and Europe due to larger overall market size and greater prevalence of urinary and fecal dysfunction.

The market for SNM therapy is large and growing. We believe that the global SNM market was approximately $650 million in 2018, which we believe is comprised of sales of SNM systems for the treatment of UUI, UUF, FI, and UR, and is growing at an approximate rate of 8% year-over-year. We believe this represents approximately 46,000 patient implants, including 10,000 patients undergoing replacement implants, with nearly 90% of sales in this market being generated in the United States and approximately 85% of sales revenue coming from new implant volume. Further, we estimate that the global annual addressable SNM market is presently approximately one percent penetrated. We estimate the global annual SNM market will continue to increase for the foreseeable future driven by increased awareness and education of SNM as a therapy alternative, greater expectations for quality of life, and improved patient attitudes toward receiving medical attention. In addition, market growth could accelerate due to more than one medical device company being focused on this market, new innovation for SNM therapy, and other potential products being introduced to physicians and patients. We believe that this represents a compelling opportunity for our r-SNM System to capture market share and further penetrate and grow the existing market.

Overview of Overactive Bladder

OAB causes a sudden urge to urinate that may be difficult to stop, and could lead to the involuntary leakage of urine. SNM therapy is a well-established third-line therapy for the treatment of certain patients' symptoms of OAB, including subtypes UUF and UUI, and UR. Based on phone-based surveys of 5,204 people conducted from November 2000 to January 2001, a study published in 2003 by Stewart WF et al. concluded that of the approximately 244 million adult population in the United States at that time, approximately 40 million, or roughly 16.5%, exhibited symptoms of OAB. Additionally, based on telephone interviews of 19,165 people conducted from April 2005 to December 2005, a study published in 2005 by Milsom et al. concluded that of the estimated 391 million adult population in Europe at that time, approximately 47 million, or roughly 11.8%, exhibited symptoms of OAB.

In the United States and Europe, symptom-specific prevalence varies significantly by gender and age. The graphic below demonstrates OAB prevalence by gender in the United States and Europe.



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 have driven continued growth in the prevalence of OAB. According to the Center for Disease Control ("CDC"), 11 states in 2000 had prevalence of obesity that exceeded 22% and this increased to 36 states that exceeded 26% by 2015. The CDC saw similar conclusions with the increase in diabetes prevalence, where in 2000, approximately half of the states had a prevalence of less than six percent, and by 2015, 27 states had exceeded nine percent.

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 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 urgency to urinate associated with OAB may be accompanied by a combination of several symptoms, including abnormally frequent urination, or frequency, that is typically defined as urinating eight or more 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 is characterized by the sudden need to urinate eight or more times per day and, when this symptom is 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 UR is the inability to empty the bladder without an obstruction, such as prostate enlargement or a stricture.

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, although the difference is not substantial. 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 ranging in age from 40 to 65 years old 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. 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

and acceptable 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. Underlying issues that can cause OAB include neurological diseases and injuries, obstructions, bladder abnormalities, and other issues.

If the physician is able to identify an underlying cause of OAB, the physician will then prescribe a care pathway 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.

In women, the largest group of OAB sufferers are idiopathic, accounting for nearly 50% of the female OAB population. The second largest category is women with mixed urinary incontinence ("MUI"), which means a patient has both stress urinary incontinence and UUI, accounting for approximately 40% of the female OAB population. While all women with idiopathic OAB can be treated with SNM therapy, based on clinical data, we estimate that approximately 40% of individuals with MUI will be candidates for SNM therapy based on the etiology of their symptoms. Accordingly, we believe that approximately 66% of women who suffer from OAB are treatable with SNM therapy.

In men, the primary causes of OAB symptoms are obstructive, in particular due to the benign enlargement of the prostate. Obstruction-related OAB accounts for over 60% of the male OAB population. Because obstruction-related OAB patients can be treated to address the underlying cause of the obstruction, these men are unlikely to be prescribed OAB medications and are generally not treatable with SNM therapy. Men who are actually diagnosed with idiopathic OAB only account for five percent of the overall population of male OAB sufferers. However, we believe that because of the prevalence of obstructive OAB in men, many men who actually suffer from idiopathic OAB (either alone or in conjunction with obstructive OAB) go undiagnosed or misdiagnosed as having solely obstructive OAB. As a result, we believe that the population of men actually diagnosed with idiopathic OAB is comprised of a disproportionate number of men who have been prescribed and failed drugs for the treatment of idiopathic OAB, because there is another segment of men who suffer from idiopathic OAB that is not accounted for in this population. Accordingly, we estimate that approximately 10% of men who suffer from OAB are treatable with SNM therapy.

OAB is associated with a significant economic burden to the 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.

Overview of Fecal Incontinence

FI is the inability to control bowel function, causing involuntary 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. We believe approximately 60% of people with FI exhibit idiopathic symptoms or experience FI as result of obstetric or surgical injury or other prior trauma, all of which can be treated with SNM therapy.

People with FI experience even greater degrees of embarrassment and decreased quality of life than people with OAB. The total FI population is estimated to be 40 million adults in the United States and Europe. We believe shifting expectations and attitudes toward medical attention suggest this addressable market has the potential to expand.

According to the American National Health and Nutrition Examination Survey program of 2005 through 2006, approximately 8.3% of the adult population in the United States exhibited symptoms of FI. Based on the estimate of the United States population in 2014 of approximately 221 million adults, approximately 18 million adults in the United States exhibited symptoms of FI. In this survey, FI prevalence was assessed as the occurrence of at least one incontinence

episode during the past month. Weekly episodes were estimated to occur in 2.7% of the population, and daily episodes in 0.9%. In addition, according to The National Institute for Health and Care Excellence in the United Kingdom, of the approximately 391 million adult population in Europe in 2007, between 1.0% and 10.0% exhibited symptoms of FI. Based on this data, we have assumed that 5.0% of the adult population in Europe at that time, or approximately 20 million people, exhibited symptoms of FI.

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. These idiopathic patients, who make up 10% of women suffering from FI and 7% of men suffering from FI, are also ideal candidates for SNM therapy.

Path to Treatment

Overactive Bladder

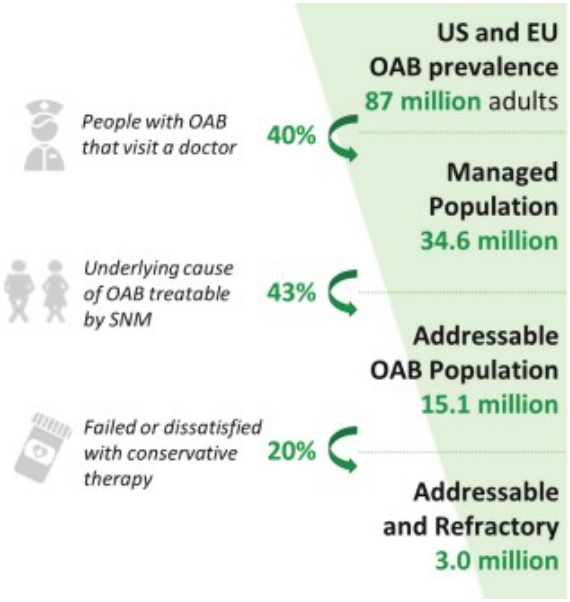
In the United States, of the approximately 40 million adult patients with symptoms of OAB, we believe that approximately 15.9 million seek medical attention, with UUI patients more frequently consulting with a physician. Similarly, in Europe, of the approximately 47 million adult patients with symptoms of OAB, we believe that approximately 18.7 million seek medical attention. As a result, we believe that the OAB population in the United States and Europe who seek medical attention for OAB, which we refer to as the managed population in the graphic below, is approximately 34.6 million.

Of the approximately 15.9 million patients who seek medical attention in the United States for the treatment of symptoms of OAB, we believe that approximately 6.8 million are addressable with SNM therapy. Similarly, in Europe, of the approximately 18.7 million patients who seek medical attention for the treatment of symptoms of OAB, we believe that approximately 8.3 million are addressable with SNM therapy. These amounts are based on our estimates that approximately 66% of women who suffer from OAB have either idiopathic OAB or MUI treatable with SNM therapy, and 10% of men who suffer from OAB have idiopathic OAB. As a result, we believe that the addressable OAB population for SNM therapy is 15.1 million patients in the United States and Europe.

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 include 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.

Of the approximately 6.8 million patients who exhibit symptoms of OAB that are addressable with SNM therapy in the United States, we estimate that approximately 1.4 million are eligible candidates for SNM therapy. Similarly, of the approximately 8.3 million patients who exhibit symptoms of OAB that are addressable with SNM therapy in Europe, we estimate that approximately 1.6 million are eligible candidates for SNM therapy. These estimates are based on seven percent of these approximately 6.8 million patients who exhibit symptoms of OAB that are addressable with SNM therapy who are currently receiving second-line drug therapies but are not satisfied with the results and are seeking alternative treatment options, and 13% of these approximately 6.8 million patients who exhibit symptoms of OAB that are addressable with SNM therapy who have failed second-line drug therapies and are seeking alternative treatment options. As a result, we believe that the addressable population that is readily treatable with and eligible candidates for SNM therapy, which we refer to as addressable and refractory in the graphic below, is approximately three million patients in the United States and Europe.

The graphic below provides a summary of the calculation of the SNM addressable and refractory population from the overall population of OAB sufferers in the United States and Europe.



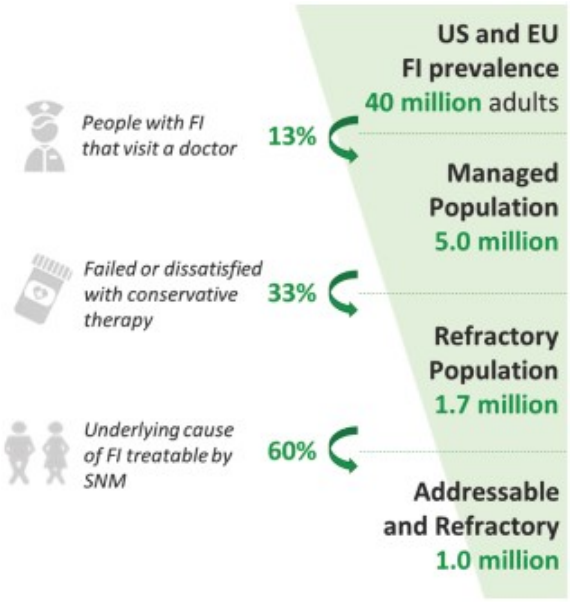
Fecal Incontinence

In the United States and Europe, based on published results from surveys of patients with FI, of the approximately 40 million adults with symptoms of FI, we believe that approximately five million people seek medical attention, which we refer to as the managed population in the graphic below.

Of the approximately five million people who seek medical attention in the United States and Europe for the treatment of symptoms of FI, we believe that approximately 1.7 million have failed or are dissatisfied with conservative treatment, which we refer to as the refractory population in the graphic below.

Of the approximately 1.7 million refractory population, we believe that approximately one million patients do not suffer from FI as a result of a condition that requires a different treatment path, such as neurological diseases, inflammatory disease and severe anatomical defects, and as such are readily treatable with and eligible candidates for, SNM therapy, which we refer to as addressable and refractory in the graphic below.

The graphic below provides a summary of the calculation of the SNM addressable and refractory population from the overall population of FI sufferers in the United States and Europe.



Current Treatments 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 PTNS.

First- and second-line therapies comprise the largest segment of the treatment market, and medication and other non-implantable treatments are better known to physicians and hospitals than SNM therapy. According to most U.S. insurance reimbursement programs, patients must try and fail at least two different medications before considering and being eligible for third-line therapies.

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, estimated at $3.6 billion in 2017. 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 is the only available beta-3-adrenergic agonist that targets the bladder muscles and reduces bladder contractions and was approved in 2012 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 a relatively new drug 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 with Mirabegron in clinical trials were hypertension, nasopharyngitis, and urinary tract infection.

Third-Line Therapies

Sacral Neuromodulation

Historically, SNM therapy has been the most common form of third-line therapy treatment for OAB. InterStim II, the only currently available SNM system, was approved to treat the symptoms of OAB by the FDA in 2005, and to treat the symptoms of FI by the FDA in 2011, and its predecessor, InterStim, was approved to treat the symptoms of OAB by the FDA in 1997 and 1999 for UUI and UUF, respectively. These systems have been implanted in over 300,000 patients worldwide, 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.

Our Solution

We believe that our proprietary r-SNM System provides a minimally invasive, effective, and long-lasting solution for SNM therapy to treat patients with urinary and fecal dysfunction. We currently have marketing approvals in Europe, Canada, and Australia for all indications, and submitted a literature-based PMA application to the FDA for OAB and UR on December 3, 2018 and for FI on March 1, 2019.

Our r-SNM System includes two implantable components and various external components.

Implantable Components for Patient

- Miniaturized rechargeable INS, which houses the electronics for the device. It is five cubic centimeters and is intended to provide two weeks of battery life between charges under normal use conditions.

- Tined four-electrode lead, which delivers current-controlled stimulation to the targeted sacral nerve. The tines help anchor the lead in its desired position.

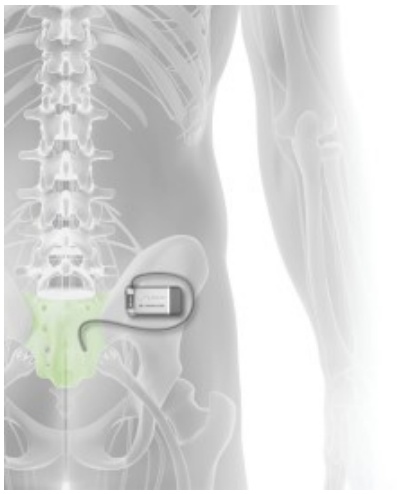
External Components for Patient

- Wireless charging device, which allows transcutaneous charging of the 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 and turn on or off stimulation. The remote control includes a light-emitting diode light that indicates therapy intensity and the status of remaining battery life of the INS.

The implantable components of our r-SNM System 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 r-SNM System, the INS and the four-electrode lead:



Benefits of our r-SNM System

We believe that our innovative and proprietary r-SNM System offers competitive advantages to InterStim II, including the following important benefits:

- **Long-term solution**. Our r-SNM System is designed to last approximately 15 years.
- **Material benefits to physicians and payors.** We believe our r-SNM System has the potential to enable physicians and facilities to utilize their resources more efficiently and significantly reduce overall costs to the healthcare system.
- **Smaller and lighter implantable neurostimulator.** Our INS is 60% smaller and half the weight of InterStim II.

- **Constant current.** Our r-SNM System delivers constant-current stimulation, automatically adapting stimulation output to the body's physical changes, which we expect will provide a more consistent and reliable therapy.

- **Improved patient experience.** Our r-SNM System charges wirelessly and includes a discrete, small and easy-to-use remote control.

- **Simplified physician implantation and programming.** Our touchscreen clinician programmer guides the implanting physician through electrode placement and stimulation programming, and enables physicians to access key data from the patient's INS.

- **Safe full-body MRI scan.** Our r-SNM System is designed to be full-body MRI scan safe. We believe that this feature will eliminate the risk and burden associated with the explant procedure that a patient may be subjected to when the patient needs an MRI scan for body part other than head, which is currently required for patients implanted with InterStim II.

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. Unlike InterStim II, the remote control used in the ETS is the same remote control used in our permanent r-SNM System. In addition, our ETS can be used for a bilateral percutaneous nerve evaluation trial or a tined lead evaluation trial. In July 2018, we received the CE Mark for our ETS.

Overview of our Physician Tools

We provide physicians with a clinician programmer and a surgical tool kit to assist them while implanting our r-SNM System. Our clinician programmer also allows physicians to connect to a patient's INS, while the patient is in the physician's care, 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 with electrode placement and stimulation programming experience for physicians. 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 r-SNM 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 r-SNM System implant procedure. The tools provided are familiar for physicians experienced in SNM implants and follow the established surgical techniques for the implant.

Treatment with our r-SNM System

Patient Selection

SNM therapy is an approved therapy for patients with symptoms of urinary and fecal 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 fecal dysfunction is indicated for patients who are not candidates for more conservative treatments. The therapy is not indicated for pregnant women, or pediatric use.

Implantation

Before receiving our r-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 system which provides stimulation for the therapy. The trial period can last between a few days and several weeks after which the physician evaluates the effectiveness of SNM therapy through several measures, including urinary or fecal episodes and patient satisfaction. Approximately 60-90% of patients proceed from trial stimulation to permanent implant depending on the trial type and patient selection.

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

Following the implant procedure or within a week thereafter, the patient has their stimulation programmed. Stimulation settings are adjusted to ensure they are comfortable to the patient. Reprogramming sessions 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

We are continuing to develop a growing body of compelling clinical evidence that demonstrates the safety, effectiveness, and sustained benefits of our r-SNM System. We have two clinical studies relating to our r-SNM System, a European study, RELAX-OAB, and a U.S. pivotal study, ARTISAN-SNM. We have implanted 51 patients in our RELAX-OAB study and 129 patients in our ARTISAN-SNM pivotal study, with approximately 100 additional patients being treated in our investigator-initiated case series and commercially.

Our RELAX-OAB study that began in June 2016 evaluated 51 patients at seven sites in Europe that suffered from OAB subtypes UUI and/or UUF. A subset of the patients suffered from both UUI and UUF. Patients in the study were directly implanted without an external trial period. Within the first month, we evaluated the patients to determine if they were a test responder to the therapy, which we refer to collectively as test responders. Patients were considered test responders if they experienced (i) for patients suffering from UUI, at least a 50% reduction in the average number of leaks per day or (ii) for patients suffering from UUF (a) at least a 50% reduction in the average number of voids per day or (b) a reduction to less than eight voids per day, in each case based on a three-day bladder diary. For the subset of patients who suffered from both UUI and UUF, if a patient qualified as a test responder for either UUI or UUF, that patient was considered a test responder to the therapy. At one month, 71% of patients were test responders to the therapy. At three, six and 12 months, OAB response rate for the test responders was 91%, 94%, and 94%, respectively, and for all patients was 71%, 72% and 72%, respectively. Test responders also experienced clinically meaningful improvements in quality of life at 12 months. In addition, at 12 months, 84% of test responders were “very” or “moderately” satisfied

with the therapy, and 100% of test responders found the duration of charging to be “very” or “moderately” acceptable. The 12-month results were published in the peer reviewed *Journal of Neurourology and Urodynamics* in January 2019. We are following patients out to two years in this study and may follow patients out to five years at selected study sites.

In June 2018, we completed the enrollment and implantation of 129 patients with UUI for our ARTISAN-SNM pivotal study. These patients are being evaluated at 14 centers in the United States and five centers in Europe. Out of 129 patients, 119 were directly implanted without an external trial period. We have determined the study’s primary endpoint to be the percentage of implanted subjects that have a therapeutic response, defined as at least a 50% reduction in the number of urgency leaks per day on a three-day bladder diary at six months post-implant. At six months, the therapy response rate was 90% for all implanted patients, and 93% of all implanted patients were “very” or “moderately” satisfied with the therapy.

An investigator-initiated case series performed in Southampton, U.K. also supports the safety and effectiveness of our r-SNM System in treating patients with FI. In this case series, 13 consecutive patients with FI were offered the choice of treatment between our r-SNM System and InterStim II. Of these 13 patients, 10 patients chose our r-SNM System over InterStim II. As a primary reason for preferring our r-SNM System, seven patients cited the small size, and three patients cited the long life or rechargeability of our r-SNM System. Similar to our clinical studies, this patient cohort did not receive an external trial period prior to system implant. According to the investigator, of the 10 patients implanted with our r-SNM System, eight patients reported clinically significant relief of symptoms and improvements in quality of life at six months.

To date, we have observed no unanticipated adverse events (“AEs”), or serious device-related AEs, in any of our clinical studies or case series. Further, the safety and effectiveness of SNM therapy when compared to anticholinergic medications was also supported by the InSite study, a prospective, randomized, multi-center study, published on January 10, 2014 in the *Journal of Neurourology and Urodynamics*. This study was sponsored by Medtronic and began in 2007 and ended in 2016, after the last patient reached the five-year endpoint.

As part of the investigational device exemption (“IDE”) approval process for our ARTISAN-SNM pivotal study, the FDA recommended that we make several modifications to the study design in order for the study to serve as the primary clinical support for a future marketing approval. In response, we have engaged with FDA regarding its recommendations. As a result, we incorporated a number of recommended study modifications. On October 19, 2018, the FDA approved our latest IDE supplement and removed certain of its prior study design recommendations. However, the FDA also continued to reiterate several of its recommended study modifications.

To date we elected not to incorporate several of the recommended modifications based on what we believe are currently accepted urology practice guidelines and the design of previous OAB clinical studies accepted by FDA. We believe certain of these modifications would have resulted in a study design that increased study site and patient burdens, decreased the feasibility of enrollment or were not clearly supported by available peer-reviewed literature or currently accepted urology practice guidelines.

Although we have not modified the ARTISAN-SNM study design to address all of the considerations that the FDA has reiterated, based on the study results to date, we believe we will be able to provide the FDA with reasonable assurance of the safety and effectiveness of our r-SNM System to support its marketing approval. Nevertheless, it is possible that the FDA could disagree with our study design and require revisions to the study or data from an additional study before approving our PMA. See “Risk Factors—Risks Related to Our Business and Strategy—We currently depend entirely on the successful and timely regulatory approval from the FDA and commercialization of our r-SNM System, our only product. Our r-SNM System may not receive FDA regulatory approval or we may be significantly delayed in receiving regulatory approval. Even if we receive regulatory approval, we may not be able to successfully commercialize our r-SNM System.”

Sales and Marketing

We are in the process of hiring a specialty sales force of approximately 100 sales professionals, regional sales managers and clinical specialists in anticipation of the commercial launch of our r-SNM System in the United States. We intend to recruit, hire and train sales representatives with strong sales backgrounds and experience in SNM therapy and other neurostimulation applications, and with relationships with urologists and urogynecologists. We intend to focus the significant majority of our sales and marketing efforts in the United States where reimbursement for SNM therapy is well established and covered by most U.S. insurers, including Medicare.

Through our specialized and dedicated direct sales organization, we plan to target the approximately 2,000 urologists, urogynecologists and colorectal surgeons who are trained and have experience performing SNM procedures. Specifically, we intend to target the estimated 1,000 physician specialists that represent a majority of the implant volume in the United States. We estimate that approximately 80% of the U.S. implant volume is generated by these 1,000 physicians.

In order to support our direct sales team, we intend to hire additional clinical support staff to expand our existing team of seven clinical support specialists. This clinical staff will be primarily responsible for attending implant procedures and assisting the implanting physician with programming the device. Based on our clinical experience to date, we believe that physicians experienced in SNM therapy require minimal training to start implanting our r-SNM System.

We also intend to promote broader awareness of SNM therapy for the treatment of OAB among patients and physicians, as well as awareness of the benefits and advantages of our r-SNM System. We plan to engage in awareness raising activities, including publication of scientific data in peer reviewed journals and education of physicians who are not familiar with or do not utilize SNM therapy. We may also engage in broad marketing initiatives in jurisdictions where we are permitted to do so.

While we have received regulatory approval in Europe, Canada, and Australia, our main commercial priority is the United States. In November 2018, we launched a limited commercial effort in Europe, where we currently have five dedicated sales representatives. We do expect to expend capital resources pursuing commercial operations in Europe, Canada and Australia, the amount and timing of which will depend on a variety of factors, including the size of the developed market for SNM therapy, burdens to entry and other region- and country-specific factors.

Third-Party Coverage and Reimbursement

In the United States, we expect to derive revenue from the sale of our r-SNM System 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 r-SNM System 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 (“AMA”). 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.

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 $21,600 to approximately $26,400, which covers the cost for the devices and the implantation procedures.

We believe that our r-SNM System and the associated procedures will be eligible for payment under the existing CPT codes typically used for SNM therapy, including CPT 64581 for transforaminal implantation of a lead near the sacral nerve and CPT 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 r-SNM System.

Research and Development

We intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System to improve patient outcomes and further expand patient access to our r-SNM therapy. Research and development expenses were approximately $19.4 million and $12.3 million for the years ended December 31, 2018 and 2017, respectively. Our goals include extending the time between recharging sessions to once a month, introducing features that would enable us to connect our INS to an already implanted InterStim II lead, and expanding the suite of product solutions available for SNM therapy over time. Additionally, we intend to pursue regulatory approval for FI in the United States in the future.

Manufacturing and Supply

We currently outsource the manufacture of the implantable components of our r-SNM System. We plan to continue with an outsourced manufacturing arrangement for the foreseeable future. Our contract manufacturers are all recognized in their field for their competency to manufacture the respective portions of our r-SNM System and have quality systems established that meet FDA requirements. We believe the manufacturers we currently utilize have sufficient capacity to meet our launch requirements and are able to scale up their capacity relatively quickly with limited capital investment.

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 r-SNM System under strict manufacturing processes supported by internal policies and procedures. We perform our own final quality control testing of each r-SNM System. 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 r-SNM System.

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 r-SNM System 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 r-SNM System. If our current third-party manufacturers cannot perform as agreed, we may be required to replace those manufacturers. 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 r-SNM System for the foreseeable future.

Competition

We believe our r-SNM System is designed to offer several needed improvements in the SNM market 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 implantable SNM devices. InterStim II is currently the only implantable SNM device 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. We face competition from major medical device companies worldwide, many of which have longer, more established operating histories and significantly greater financial, technical, marketing, sales, distribution, and other resources. 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 and approved indications;
- product safety, reliability and durability;
- INS size, rechargeability and battery life;
- full-body MRI scan safety;
- 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 r-SNM System on price both directly, through rebates and promotional programs to high volume physicians and coupons to patients, and indirectly, through attractive product bundling with complimentary 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 r-SNM System. Our competitors may seek to discredit our r-SNM System 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. 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 r-SNM System.

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 r-SNM System and we licensed several issued patents and patent applications from AMF in 2013 pursuant to the License Agreement. As of December 31, 2018, we wholly owned 19 issued U.S. patents and 22 issued foreign patents, and 15 pending U.S. patent applications and 57 pending foreign patent applications. We also license from AMF 30 issued U.S. patents and four pending U.S. patent applications, as well as 41 issued foreign patents and 25 pending foreign patent applications. Issued patents owned or used by us will expire between 2023 and 2037.

There is no active patent litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent infringement.

In addition, we own or have rights to trademarks that we use in connection with the operation of our business. We own or have rights to trademarks for our r-SNM System in the United States and select locations internationally.

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 granted us a royalty-bearing, sublicensable license to the AMF IP. The license to the AMF IP allows Axonics to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of:

(i) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body;

(ii) chronic pain in humans through the application of electrical energy to the nervous system; and

(iii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve,

excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system.

We have the right to expand the field of use for the AMF Licensed Products to modulation of digestive process and treatment of digestive conditions in humans through the application of electrical energy anywhere in or on the body, subject to the exclusions described above.

Generally, the license is non-transferable without the prior written consent of AMF, except to an affiliate of our company or in connection with the acquisition of our company (whether by merger, consolidation, sale or otherwise) or the part of our business to which the License Agreement relates, provided that the assignee agrees in writing to be bound to the terms of the License Agreement to which we are bound.

We granted to AMF a royalty-free, worldwide, sublicensable, perpetual, exclusive license to any patent rights controlled by us that arise out of our improvements to the inventions claimed in the AMF IP (the “Axonics Licensed IP”). This license granted by us to AMF explicitly excludes uses of the Axonics Licensed IP that are within the scope of the exclusive license of the AMF IP granted by AMF to us. Such license is irrevocable unless we terminate the License Agreement and AMF does not agree to pay us compensation for such license mutually agreed between us and AMF or determined by arbitration in accordance with the terms of the License Agreement. To date, we have not made any improvements to the inventions claimed in the AMF IP that constitute Axonics Licensed IP.

In addition, the License Agreement provides AMF with the option (the "AMF Option"), to license from us any intellectual property owned by us or otherwise in our control, that is related to electrical stimulation of human tissue, separate from the Axonics Licensed IP and AMF IP, on terms that are materially consistent with the terms upon which we license the AMF IP pursuant to the License Agreement, and subject to field of use restrictions that would be determined upon the exercise of the AMF Option. AMF has expressly declined in writing to exercise the AMF Option.

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF the greater of (i) 4% of all net revenue derived from the AMF Licensed Products, and (ii) a minimum annual royalty (the "Minimum Royalty"), payable quarterly. As of December 31, 2018, we have accrued $0.1 million toward the Minimum Royalty. The Minimum Royalty will automatically increase each year after 2018, subject to a maximum amount of $200,000 per year. We have 60 days to pay AMF the royalty amount due under the License Agreement, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

The initial term of the License Agreement is from October 1, 2013 to October 1, 2033, and will automatically continue until all patents are no longer in force. Upon completion of the initial term, the license granted pursuant to the License Agreement will be fully paid-up and perpetual except that if we wish to continue to practice any of the patents licensed to us by AMF that remain in force after such initial term, then we will have to continue to pay a reduced royalty for so long as such patent remains in force.

Each party may terminate the License Agreement if the other party commits a material breach of any obligation under the License Agreement and such breach is not cured within 90 days following receipt of notice of such breach from the other party. AMF may terminate the License Agreement upon (i) notice to us in the event we challenge or assist any other person or entity in challenging the patentability, enforceability or validity of any of the AMF patents licensed to us under the License Agreement, subject to certain exceptions including challenges that we are not infringing any such AMF patent, and (ii) upon our filing of or the institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of our assets for the benefit of creditors, and in the case of involuntary bankruptcy, in the event we consent to such bankruptcy and it is not dismissed within 90 days. Lastly, we may terminate the License Agreement in full for any reason effective upon 60 days written notice to AMF.

The License Agreement was amended twice in February 2014 in order to, among other things, include the field of the treatment of urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, within the scope of the licenses granted therein.

The agreement allows for AMF the right to use the AMF IP for non-commercial research, educational and scholarly purposes.

As of December 31, 2018, AMF holds 2,102,970 shares of our common stock. John Petrovich, a former member of our board of directors who retired from the board in early March 2019, is the President, Chief Executive Officer, Senior Vice President, Business Development and General Counsel of AMF.

The protection of intellectual property has been and remains a priority for us. For more information, please see "Risk Factors—Risks Related to Intellectual Property Matters."

Government Regulation Applicable to Us

Our r-SNM System and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, including the United States Federal Communications Commission ("FCC"), as well as comparable authorities in the European Economic Area ("EEA"). Our r-SNM System is 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 governing clinical studies and the commercial sales and distribution of our r-SNM System. Whether or not we have or are required to obtain FDA

clearance or approval for a product, we will be required to obtain authorization before commencing clinical studies and to obtain marketing authorization or approval of our product under the comparable regulatory authorities of countries outside of the United States before we can commence clinical studies or commercialize our product in those countries. 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 therefore are not eligible for 510(k) review but project a low-to-moderate risk may be eligible for the de novo review process.

We believe our r-SNM System is a Class III device that will require PMA approval in order to be lawfully marketed in the United States.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed. In a PMA, the manufacturer must demonstrate that the device is safe and effective. 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 the applicable portions of the Quality Systems Regulation ("QSR").

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and effectiveness data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

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 supplement or PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Studies

Clinical studies are typically required to support a PMA. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical studies. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the applicant that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical study to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board ("IRB") for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical studies may begin at a specific number of investigational sites with a cap on a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical study after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical studies. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical study at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

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;
- FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;

- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with health care providers;

- the federal 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 federal 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, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device 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 (“GUDID”);

- the FDA’s recall authority, whereby the agency can under certain circumstances order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; 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.

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance.

Our manufacturing processes will be required to comply with the applicable portions of the QSR, which covers the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master record, device history file, and complaint files. As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our r-SNM System.

The discovery of previously unknown problems with our r-SNM System, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its approval, could result in restrictions on the device, including the removal of our r-SNM System from the market or voluntary or mandatory device recalls.

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 r-SNM System 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 r-SNM System or future product candidates; or
- criminal prosecution.

Regulation of Medical Devices in the EEA

Medical devices, other than active implantable medical devices ("AIMDs"), placed on the market in the EEA (which is comprised of the 28 Member States of the 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. We believe that our r-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.

On April 5, 2017, the European Parliament adopted the Medical Devices Regulation (Regulation 2017/745), which will repeal and replace both AIMD and Medical Devices Directives. The Medical Devices Regulation 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.

The Medical Devices Regulation will only become applicable after the three-year transition period ends on May 26, 2020. Up until this date, conformity certificates can continue to be issued validly by Notifiable Bodies under the AIMD and Medical Devices Directives. Alternatively, during the three-year transition period, manufacturers can choose to conform with and have their products certified under the Medical Devices Regulations. Certificates of compliance issued pursuant to these Directives prior to May 26, 2020 will continue to be valid for up to a period of 4 years. However, after May 26, 2020, new products placed on the market may only be certified under the Medical Device Regulations regime. This new regime will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

United Kingdom's Vote to Leave the EU

The withdrawal of the United Kingdom from the EU will take effect either on the effective date of the withdrawal agreement or, in the absence of an agreement, two years after the United Kingdom provided its notice of withdrawal. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to EU markets either during a transitional period or more permanently. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the referendum could materially change the regulatory regime applicable to products approved and sold in the United Kingdom. It is possible that there will be greater restrictions on imports and exports between the United Kingdom and EU countries, increased regulatory complexities, and economic and political uncertainty in the region. Because of the continued uncertainty about the effects, implementation, or potential repeal of Brexit, we cannot quantify or predict with any certainty the likely impact of Brexit or related legislation on our business, financial condition, and results of operations.

In addition, in event of Brexit, European and worldwide economic or market conditions will be affected, which could lead to instability in global financial markets. Brexit is likely to lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which EU laws to replace or replicate. Any of these

effects of Brexit, and others we cannot anticipate, could adversely affect our business, financial condition, and results of operations.

Regulation of Medical Devices in Other Jurisdictions

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our r-SNM System, including in the areas of:

- design, development, manufacturing and testing;
- product standards;
- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical studies;
- record keeping procedures;
- advertising and promotion;
- recalls and field 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;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement; and
- necessity of testing performed in country by distributors for licensees.

The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal 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 stock, stock options, and the compensation derived through ownership interests.

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the United States Department of Health and Human Services issued regulations in July 1991, which the Department has referred to as “safe harbors.” These safe harbor regulations set forth certain provisions which, 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. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. 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 narrowly. Our arrangements with physicians, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (described below).

Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $74,792 (in 2017) for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. Liability under the federal Anti-Kickback Statute may also arise because of the intentions or actions of the parties with whom we do business. While we are not aware of any such intentions or actions, we have only limited knowledge regarding the intentions or actions underlying those arrangements. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. The majority of states also have anti-kickback laws which establish similar prohibitions, and in some cases, may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil 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, such as a rebate. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act.

In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. Penalties for federal civil False Claim Act violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program. On May 20, 2009, the Fraud Enforcement Recovery Act of 2009 ("FERA"), was enacted, which modifies and clarifies certain provisions of the federal civil False Claims Act. In part, the FERA amends the federal civil False Claims Act such that penalties may now apply to any person, including an organization that does not contract directly with the government, who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim paid in part by the federal government. The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or 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.

The Health Insurance Portability and Accountability Act ("HIPAA") also created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our r-SNM System and any future product candidates is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our r-SNM System and any future product candidates to the general public and may impose limitations on our promotional activities with healthcare professionals. Also, many U.S. states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. The federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or Children's Health Insurance Program for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of $11,052 per failure up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for "knowing failures"). Manufacturers must submit reports by the 90th day of each calendar year. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

FCC Regulation

Because our r-SNM System includes a wireless radio frequency transmitter and receiver, it is 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.

We intend to submit an equipment certification application for non-experimental use to the FCC for our r-SNM System. Any modifications to our r-SNM System after FCC approval, if obtained, may require new or further FCC approval before we are permitted to import, market and sell a modified system, and it could take several months to obtain any necessary FCC approval. FCC approval has no impact on whether we will receive PMA approval.

Data Privacy and Security Laws

We are also subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act ("HITECH"), in the United States.

HIPAA established uniform standards governing the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to comply with standards that include the privacy and security of protected health information ("PHI"). HIPAA also requires business associates, such as independent contractors or agents of covered entities that have access to PHI in connection with providing a service to or on behalf of a covered

entity, of covered entities to enter into business associate agreements with the covered entity and to safeguard the covered entity's PHI against improper use and disclosure.

The HIPAA privacy regulations cover the use and disclosure of protected health information by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit protected health information on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered entity, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose protected health information is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information or insofar as such state laws apply to personal information that is broader in scope than protected health information as defined under HIPAA.

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured PHI. If notification to patients of a breach is required, such notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, we would be required to report the improper use or disclosure to the U.S. Department of Health and Human Services ("HHS"), which would post the violation on its website, and to the media. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to 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 such as those for 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, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

In the EU, we may be subject to laws relating to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the EU includes the General Data Protection Regulation ((EU) 2016/679) ("GDPR"), regarding the processing of personal data and the free movement of such data, 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 became applicable on May 25, 2018, replacing the previous data protection laws issued by each EU member state based on the Directive 95/46/EC. Unlike the Directive (which needed to be transposed at national level), the GDPR text 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 also be adequate, relevant, not excessive in relation to the purposes for which it is collected, 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. To the extent that we process, control or otherwise use special categories of personal data relating to living individuals (for example, patients' health or medical information), more stringent rules apply, limiting 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 additionally imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. 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. The GDPR provides that EU member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business.

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

We depend on a number of third parties in relation to our provision of our services, a number of which process personal data on our behalf. With each such provider we enter into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place, and that they comply with the other contractual requirements for third party data processors set out in the GDPR. Where we transfer personal data outside the EEA, we do so in compliance with the relevant data export requirements. We take our data protection obligations seriously, as any improper disclosure, particularly with regard to our customers' sensitive personal data, could negatively impact our business and/or our reputation.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our r-SNM System or any future product candidates profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our r-SNM System or future product candidates. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our r-SNM System or future product candidates.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. The Affordable Care Act also provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare payments to providers of two percent per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative

amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our r-SNM System or future product candidates or additional pricing pressure.

Anti-Bribery and Corruption Laws

Our operations in the United States are subject to the Foreign Corrupt Practices Act ("FCPA"). We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. 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 anticorruption legislation implemented in Europe under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

Employees

As of December 31, 2018, we had 87 employees. 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.

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 commenced our operations in late 2013 when we entered into the License Agreement. Our principal executive offices are located at 26 Technology Drive, Irvine, California 92618 and our telephone number is (949) 396-6322. Our website is www.axonicsmodulation.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, and you should not consider any information contained on, or that can be accessed through, our website as part of this Annual Report on Form 10-K or in deciding whether to purchase our common stock.

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.axonicsmodulation.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 common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information included 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 the following 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.

Risks Related to Our Business and Strategy

We currently depend entirely on the successful and timely regulatory approval from the FDA and commercialization of our r-SNM System, our only product. Our r-SNM System may not receive FDA regulatory approval or we may be significantly delayed in receiving regulatory approval. Even if we receive regulatory approval, we may not be able to successfully commercialize our r-SNM System.

We currently have only one product, our r-SNM System, and our business presently depends entirely on our ability to obtain regulatory approval from the FDA for our r-SNM System and to successfully commercialize it in a timely manner. We have no other products currently approved for sale and we may never be able to develop marketable products or enhancements to our r-SNM System. We are not permitted to market our r-SNM System in the United States until we receive approval from the FDA. We do not know if or when we will receive such approval or whether we will need to make modifications to our r-SNM System, generate additional data to submit to the FDA, or incur significant additional expenditures to obtain any such approval.

Our near-term prospects, including our ability to finance our company and generate revenue, as well as our future growth, depend entirely on the successful and timely regulatory approval from the FDA and commercialization of our r-SNM System. The regulatory and commercial success of our r-SNM System will depend on a number of factors, including the following:

- whether we are required by the FDA or other similar regulatory authorities to conduct additional clinical studies or to modify the design of our current studies to support the approval of our r-SNM System;
- our success in educating physicians and patients about the benefits, administration and use of our r-SNM System;
- the timely receipt of necessary marketing approvals from the FDA and other similar regulatory authorities;
- achieving and maintaining compliance with all regulatory requirements applicable to our r-SNM System;
- the ability to raise additional capital on acceptable terms, or at all, if needed, to support the commercial launch of our r-SNM System;
- the acceptance by physicians and patients of the safety and effectiveness of our r-SNM System;
- our ability to successfully commercialize our r-SNM System;
- our ability to hire a sufficient number of talented sales representatives to sell our r-SNM System;
- the ability of our current manufacturers and any third parties with whom we may contract to manufacture our r-SNM System to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with applicable requirements; and
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of competing products, such as InterStim II, or competing third-line therapies, such as BOTOX injections and PTNS.

For example, as part of the IDE approval process for our ARTISAN-SNM pivotal study, the FDA recommended that we should make several modifications to the study design in order for the study to serve as the primary clinical support for a future marketing approval. Specifically, despite our responses and supporting documentation that we submitted in support of our study design, the FDA reiterated its previously expressed recommendations that we make the following modifications to our ARTISAN-SNM pivotal study:

- exclude patients with mixed urinary incontinence (“MUI”), which means a patient has both stress urinary incontinence and UUI;
- use either a seven-day bladder diary or two separate three-day bladder diaries;
- use a 12-month primary effectiveness endpoint in order to account for the placebo effect and enable assessment of durability of the treatment effect;
- use all patients in whom an implant is attempted, not initial responders after one month, for primary efficacy analysis;

- use multiple imputation to account for missing primary endpoint data;
- revise the protocol to include details on statistical analysis methods for analyzing the primary and secondary endpoints, analysis population, method for handling missing endpoint data and sensitivities and poolability analyses;
- use a two-sided 95% confidence interval; and
- provide further justification for restarting with a new activation date after a lead issue.

In response, we engaged with the FDA regarding its recommendation, including our latest IDE supplement, which we submitted to the FDA in September 2018 to address certain of its recommendations. As a result, we incorporated a number of recommended study modifications. However, to date we elected not to incorporate several of the recommended modifications based on what we believe are currently accepted urology practice guidelines and the design of previous OAB clinical studies accepted by the FDA. We believe certain of these modifications would have resulted in a study design that increased study site and patient burdens, decreased the feasibility of enrollment or were not clearly supported by available peer-reviewed literature or currently accepted urology practice guidelines. At this point in the study, some of the FDA's recommendations cannot be implemented. For example, we cannot exclude patients with MUI and we cannot change the three-day bladder diaries taken at baseline to seven-day bladder diaries. On October 19, 2018, the FDA approved our latest IDE supplement and removed certain of its prior study design recommendations while reiterating several others. On November 9, 2018, we filed an additional IDE supplement with the FDA regarding certain of its reiterated recommendations, and the response from the FDA is pending.

We completed enrollment of patients for the ARTISAN-SNM study in June of 2018. The approved protocol from the FDA based on our September 2018 IDE supplement incorporated certain of the FDA's recommended study design considerations. Although we have not modified the ARTISAN-SNM pivotal study design to address all of the considerations that the FDA has reiterated, based on the study results to date, we believe we will be able to satisfy the FDA with reasonable assurance of the safety and effectiveness of our r-SNM system to support its marketing approval. However, it is possible that the FDA may not consider the results to be sufficiently strong or that, in part due to its concerns with our study design, the FDA will not accept the data as a reasonable assurance of safety and effectiveness, which would materially and adversely affect our ability to obtain marketing approval of our r-SNM System. If we intend to modify the study design to address any of the above FDA considerations that we have not already addressed, we will be required to obtain FDA approval of an IDE supplement before implementing the changes, which could result in significant delays. The approval requirements for an IDE supplement are generally the same as an original IDE, and they are approved if the FDA does not object within 30 days. We would also be required to get IRB approval of the protocol changes if the changes involve the rights, safety, or welfare of the patients, and some investigators may determine that local rules require additional approvals from a local IRB.

In addition, incorporating modifications may be costly or not possible at this point in the ongoing clinical study or lead to delays in obtaining approval from the FDA, which may be significant and adversely and materially affect our ability to successfully commercialize our r-SNM System. Further, even if we make changes to the study design to address these considerations, the FDA may not approve our r-SNM System.

We initially submitted a literature-based PMA on January 9, 2018, in which we claimed equivalence to InterStim II based on the review of technical specifications, published clinical studies, and other information. On May 9, 2018, the FDA responded to our initial literature-based PMA and requested that we submit additional information to demonstrate that our r-SNM System is sufficiently similar to InterStim II, as well as asking us to address a number of other matters. On October 18, 2018, we responded to the FDA and withdrew our initial literature-based PMA. On December 3, 2018, we submitted a new literature-based PMA claiming equivalence to InterStim II. This literature-based PMA was based on reasonable safety and effectiveness data from a literature review. In this PMA filing, we submitted existing literature reporting on InterStim II. In addition to the technical specifications, testing data and published literature, we included one-year follow-up data from our 51-patient RELAX-OAB European post-market clinical follow-up study to support the PMA, and subsequently provided the FDA with the clinical results on the first 60 patients to reach their six-month primary endpoint from our ARTISAN-SNM pivotal study. This PMA filing incorporates all elements of the r-SNM System, the External Trial System, and related accessories, as well as the additional information addressing FDA's questions in its May 9, 2018 correspondence. Since the PMA submission on December 3, 2018, we have submitted various amendments to the PMA. These amendments include data in support

of conditional full-body MRI labeling, and complete three-month and six-month clinical data from the ARTISAN-SNM study.

In addition to this, on March 1, 2019, we submitted a new literature-based PMA seeking approval for FI. This PMA is also based on an existing literature review of Interstim II.

If we do not successfully address the FDA's suggested considerations or other questions that arise during the FDA review process and obtain FDA approval, and for some changes, obtain IRB approval, in a timely manner or at all, we could experience significant delays in obtaining marketing approval from the FDA for our r-SNM System or not obtain approval at all. Even if FDA regulatory approval is obtained, we may never be able to successfully commercialize our r-SNM System.

We have derived minimal revenue from our operations and incurred significant operating losses since inception, 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 operating history. To date, we have invested substantially all of our efforts in the research and development of, seeking regulatory approval for, and commercial planning for our r-SNM System. We are not profitable and have incurred losses each year since we began our operations in 2013. We have a limited operating history upon which to evaluate our business and prospects. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history or an approved product on the market in the United States. To date, we have not obtained regulatory approval for our r-SNM System in the United States or generated meaningful revenue from sales of our r-SNM System outside the United States.

We have not derived meaningful revenue from our operations, as our activities have consisted primarily of developing our technology and conducting clinical studies. As a result, we have recorded net losses of $32.5 million and $18.1 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $99.6 million. To date, we have financed our operations through equity financings, including our October 2018 initial public offering ("IPO"), and amounts borrowed under our Loan Agreement (defined below). We have devoted substantially all of our financial resources to research and development activities as well as general and administrative expenses associated with our operations, including clinical and regulatory initiatives to obtain marketing approval.

We expect that our operating expenses will continue to increase as we (i) build our commercial infrastructure, (ii) develop, enhance, seek FDA regulatory approval for, and begin to commercialize, if approved, our r-SNM System in the United States, (iii) increase our commercialization efforts internationally, and (iv) incur additional operational costs associated with being a public company. For example, we are in the process of hiring a specialty sales force of approximately 100 sales professionals, regional sales managers and clinical specialists in advance of the anticipated commercial launch of our r-SNM System in the United States, and expect to grow our sales force over time and the number of our sales representatives at commercial launch will vary and may be higher depending on the duration of the PMA review process. If we are delayed in obtaining approval of our r-SNM System by the FDA, we may be required to offer increased compensation to our U.S. sales team in order to retain them, which would further increase our operational costs. As a result, we expect to continue to incur operating losses for the foreseeable future. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

If approved by the FDA, we expect that sales of our r-SNM System will account for the substantial majority of our future revenue. If our r-SNM System does not achieve an adequate level of acceptance by physicians, health care payors, and patients and does not receive adequate reimbursement from third party payors, we may not generate sufficient revenue and we may not be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability in subsequent periods or on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material and adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline.

Our r-SNM System is currently our sole product, and we are completely dependent on the success of our r-SNM System. We have limited experience marketing and selling our r-SNM System, and we may have difficulty commercializing our r-SNM System and generating product revenue.

Our r-SNM System is currently our sole product, and we are completely dependent on its success. Successfully commercializing medical devices such as ours is a complex and uncertain process. Our commercialization efforts will 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:

- our ability to successfully obtain regulatory approval in the United States for our r-SNM System for the treatment of UUI;
- the effectiveness of our marketing and sales efforts in the United States and internationally;
- our third-party manufacturers' and suppliers' ability to manufacture and supply the components of our r-SNM System in a timely manner and in accordance with our specifications;
- 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 r-SNM System;
- the emergence of competing technologies and other adverse market developments, and our need to enhance our r-SNM System and/or develop new products to maintain market share in response to such competing technologies or market developments;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our r-SNM System; and
- our ability to successfully conduct additional clinical studies as may be required by the FDA or comparable non-U.S. regulatory authorities to enable our r-SNM System to be approved for additional indications.

We currently have a limited sales and marketing organization outside the United States and are in the process of building our sales and marketing organization in the United States. We began marketing and selling our r-SNM System in certain limited European markets in 2018. As a result, we have limited experience marketing and selling our r-SNM System. We currently sell our r-SNM System through a limited direct sales force in Europe, that targets physicians and hospitals. As of December 31, 2018, our limited direct sales organization in Europe consisted of five employees.

In order to generate future revenue growth, we plan to expand the size and geographic scope of our sales and marketing organization. Our future success will depend largely on our ability to hire, train, retain and motivate skilled sales, marketing and reimbursement personnel with significant industry experience and technical knowledge of implantable devices and related products. Because the competition for their services is high, we may not be able to hire and retain additional personnel on favorable or commercially reasonable terms. If we are delayed in obtaining approval of our r-SNM System by the FDA, we may be required to offer increased compensation to our U.S. sales team in order to retain them. Notwithstanding, we may lose members of our sales team who do want or are not able to wait until we obtain approval from the FDA without actively selling our product or earning less than they would otherwise if our product were approved in the United States. Our failure to hire or retain qualified sales, marketing and reimbursement personnel would prevent us from expanding our business and generating revenue.

Once hired, the training process for sales representatives can be lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with our product expected by physicians. Upon completion of the training, we expect that the sales representatives would require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent we hire personnel 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.

If we are not successful in recruiting sales, marketing and reimbursement personnel or building a sales and marketing infrastructure, we will have difficulty successfully commercializing our r-SNM System, which would adversely affect our business, operating results and financial condition. If we are not successful in commercializing our r-SNM System, our future product revenue will suffer and we would likely incur significant additional losses. Any factors that adversely impact the commercialization of our r-SNM System will have a negative impact on our business, results of operations and financial condition.

We will require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. As a result, we may not be able to implement our planned sales and marketing program to increase the adoption of our r-SNM System.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development activities and conducting clinical studies for our r-SNM System. We expect these activities and the associated expenses to continue. We also expect our expenses to increase substantially in connection with our plan to commercialize our r-SNM System in the United States and hire qualified personnel. Additional expenditures will 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.

As of December 31, 2018, we had cash, cash equivalents and short-term investments of $157.5 million. We believe that the net proceeds from our IPO, together with our existing cash, cash equivalents and short-term investments, will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months.

Our present and future funding requirements will depend on many factors, including:

- our ability to successfully obtain regulatory approval in the United States for our r-SNM System for the treatment of UUI and the associated costs;
- the costs associated with manufacturing, selling, and marketing our r-SNM System for the treatment of UUI in the United States, if approved by the FDA, and for other indications for which we receive regulatory clearance or approval, including the cost and timing of implementing our sales and marketing plan and expanding our manufacturing capabilities;
- our ability to effectively market and sell, and achieve sufficient market acceptance and market share for, our r-SNM System;
- the costs to establish, 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;
- the emergence of competing technologies and other adverse market developments, and our need to enhance our r-SNM System 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 time and cost necessary to complete post-market studies that could be required by regulatory authorities or other studies required to obtain clearance for additional indications;
- the timing, receipt, and amount of license fees and sales of, or royalties on, or future improvements on our r-SNM System, if any; and
- our need to implement additional internal systems and infrastructure, including financial, compliance, and reporting systems, incidental to being a public company.

We may need to raise additional capital or alternatively we may seek to raise only equity capital. 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 r-SNM System, 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 rely on the License Agreement to provide us with rights to use the AMF IP to develop and commercialize the AMF Licensed Products, which are used in our r-SNM System. Any termination or loss of significant rights under the License Agreement would materially and adversely affect our development and commercialization of our r-SNM System.

On October 1, 2013, we entered into the License Agreement pursuant to which AMF granted us a royalty-bearing, sublicensable license to the AMF IP. The license to the AMF IP allows Axonics to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of:

(i) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body;

(ii) chronic pain in humans through the application of electrical energy to the nervous system; and

(iii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve,

excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system.

We have the right to expand the field of use for the AMF Licensed Products to modulation of digestive process and treatment of digestive conditions in humans through the application of electrical energy anywhere in or on the body, subject to the exclusions described above.

Generally, the license is non-transferable without the prior written consent of AMF, except to an affiliate of our company or in connection with the acquisition of our company (whether by merger, consolidation, sale or otherwise) or the part of our business to which the License Agreement relates, provided that the assignee agrees in writing to be bound to the terms of the License Agreement to which we are bound.

We granted to AMF a royalty-free, worldwide, sublicensable, perpetual, exclusive license to the Axonics Licensed IP. This license granted by us to AMF explicitly excludes uses of the Axonics Licensed IP that are within the scope of the exclusive license of the AMF IP granted by AMF to us. Such license is irrevocable unless we terminate the License Agreement and AMF does not agree to pay us compensation for such license mutually agreed between us and AMF or determined by arbitration in accordance with the terms of the License Agreement. To date we have not made any improvements to the inventions claimed in the AMF IP that constitute Axonics Licensed IP.

In addition, the License Agreement provides AMF with the AMF Option, to license from us any intellectual property owned by us or otherwise in our control that is related to electrical stimulation of human tissue, separate from the Axonics Licensed IP and AMF IP, on terms that are materially consistent with the terms upon which we license the AMF IP pursuant to the License Agreement, and subject to field of use restrictions that would be determined upon the exercise of the AMF Option. AMF has expressly declined in writing to exercise the AMF Option.

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF the greater of (i) 4% of all net revenue derived from the AMF Licensed Products, and (ii) a minimum annual royalty (the "Minimum Royalty"), payable quarterly. As of December 31, 2018, we have accrued $0.1 million toward the Minimum Royalty. The Minimum Royalty will automatically increase each year after 2018, subject to a maximum amount of $200,000 per year. We have 60 days to pay AMF the royalty amount due under the License Agreement, and if we fail

to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

The initial term of the License Agreement is from October 1, 2013 to October 1, 2033, and will automatically continue until all patents are no longer in force. Upon completion of the initial term, the license granted pursuant to the License Agreement will be fully paid-up and perpetual except that if we wish to continue to practice any of the patents licensed to us by AMF that remain in force after such initial term, then we will have to continue to pay a reduced royalty for so long as such patent remains in force.

Each party may terminate the License Agreement if the other party commits a material breach of any obligation under the License Agreement and such breach is not cured within 90 days following receipt of notice of such breach from the other party. AMF may terminate the License Agreement upon (i) notice to us in the event we challenge or assist any other person or entity in challenging the patentability, enforceability or validity of any of the AMF patents licensed to us under the License Agreement, subject to certain exceptions including challenges that we are not infringing any such AMF patent, and (ii) upon our filing of or the institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of our assets for the benefit of creditors, and in the case of involuntary bankruptcy, in the event we consent to such bankruptcy and it is not dismissed within 90 days. Lastly, we may terminate the License Agreement in full for any reason effective upon 60 days written notice to AMF.

The License Agreement was amended twice in February 2014 in order to, among other things, include the field of the treatment of urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, within the scope of the licenses granted therein.

The agreement allows for AMF the right to use the AMF IP for non-commercial research, educational and scholarly purposes.

As of December 31, 2018, AMF holds 2,102,970 shares of our common stock. John Petrovich, a former member of our board of directors who retired from the board in early March 2019, is the President, Chief Executive Officer, Senior Vice President, Business Development and General Counsel of AMF.

We are reliant on a single product and if we are not successful in commercializing our r-SNM System our business will not succeed.

Our success depends completely on our r-SNM System, which is our sole product. We currently have no other product available for sale. If our r-SNM System is not successful at a level sufficient to generate a profit and we are unable to develop additional products or compelling enhancements to our r-SNM System to generate additional profit, our business will not succeed.

For over 20 years, physicians and patients have relied on the only approved SNM therapy offered by Medtronic, InterStim II and its predecessor, InterStim. As our r-SNM System will be a new product 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 r-SNM System. Physicians and patients may choose not to adopt our r-SNM System for a number of reasons, including:

- familiarity with InterStim II or preference for any new device for the treatment of SNM that Medtronic could develop and commercialize in the future;
- inability to use our r-SNM System on-label for additional unapproved indications;
- lack of experience with our r-SNM System and with SNM as a treatment alternative;
- our inability to convince key opinion leaders to provide recommendations regarding our r-SNM System, or to convince physicians and patients that it is an attractive alternative to InterStim II and other third-line therapies such as BOTOX injections and PTNS;
- perceived or actual benefits of InterStim II;
- perceived inadequacy of evidence supporting the clinical benefits or cost-effectiveness of our r-SNM System over existing alternatives;

- inability to charge our r-SNM System or preference for a non-rechargeable device, such as InterStim II;
- 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 r-SNM System.

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 r-SNM System, 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 intend to focus the majority of our sales and marketing efforts in the United States where reimbursement for SNM therapy is well established and covered by most major U.S. insurers. We are in the process of building a dedicated direct sales organization, which will initially target the estimated 1,000 physician specialists that represent a majority of the implant volume in the United States. We estimate that approximately 80% of U.S. implant volume is generated by these 1,000 physicians. We are in the process of hiring a specialty sales force of approximately 100 sales professionals, regional sales managers and clinical specialists in advance of the anticipated commercial launch of our r-SNM System in the United States. In addition, we plan to expand our current sales team into select international markets.

We also expect to conduct direct-to-patient marketing efforts to drive patient awareness of SNM therapy in general and our r-SNM System in particular. We believe that approximately 40% of people in the United States and Europe with OAB seek treatment, as they may be embarrassed to talk to their doctor about their symptoms and may even believe that their symptoms are untreatable. We intend to educate patients on the availability of SNM therapy as a treatment for the symptoms of OAB and FI in an effort to promote dialogue between patients and physicians about the existence of these symptoms in the first instance. Simultaneously we intend to educate physicians on the material benefits of our r-SNM System over InterStim II, which include, among others, longer battery life, smaller and lighter INS, constant current technology, improved patient experience, and simplified physician implantation and programming. We believe that educating healthcare providers and patients about the clinical merits and patient benefits of our r-SNM System as a treatment for OAB will be key elements driving adoption of our r-SNM System. 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 r-SNM System will require significant resources and we may never be successful. If healthcare providers and patients do not adopt our r-SNM System, and our r-SNM System does 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.

We will compete against other companies offering first-, second- and third-line therapies for the treatment of OAB, 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 r-SNM System is designed to offer several needed improvements in the SNM market 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 implantable SNM devices. InterStim II is currently the only implantable SNM device 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. We face competition from major medical device companies worldwide, many of which have longer, more established operating histories and significantly greater financial, technical, marketing, sales, distribution, and other resources. 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 and approved indications;
- 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 r-SNM System on price both directly, through rebates and promotional programs to high volume physicians and coupons to patients, and indirectly, through attractive product bundling with complimentary 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 r-SNM System. Our competitors may seek to discredit our r-SNM System 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. 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 r-SNM System.

We intend to compete against InterStim II and any future commercially available implantable SNM devices by offering material advantages over existing technology. Such advantages may not be readily adopted by the market and we may need to compete based on price or other factors, at which we may be unsuccessful.

We believe that our r-SNM System's innovative and proprietary design offers significant competitive and functional advantages over InterStim II. We believe that our r-SNM System is the first and only system for SNM therapy with a rechargeable INS battery that is designed to last approximately 15 years. As a result, patients implanted with our r-SNM System do not need to undergo replacement surgery every three to five years, as is the case for patients implanted with the non-rechargeable InterStim II. Our proprietary method of combining ceramic and titanium for the INS enclosure enables us to incorporate a significantly smaller recharging coil into our INS, which offers benefits such as 60% smaller size and half the weight of InterStim II and enhanced communication range. In addition, our r-SNM System employs constant current, automatically adapting stimulation output to the body's physiological changes, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. Further, our r-SNM System is differentiated by significant wireless charging benefits and an easy-to-use patient remote control. Finally, we designed and custom built a touchscreen clinician programmer that guides the implanting physician through electrode placement and stimulation programming. Our clinician programmer allows physicians to connect to a patient's INS, while the patient is in the physician's care, to access key therapy data that is stored and maintained on the INS.

However, these advantages may not be perceived as well as we expect by patients and physicians. As a result, we may need to compete on the basis of price or other factors, which may negatively impact market reaction to our r-SNM System. For example, the decreasing prices may cause patients and physicians to perceive our r-SNM System to be of lower quality than InterStim II, which could limit widespread adoption and acceptance of our r-SNM System.

Moreover, price competition would also likely render sales of our r-SNM System less profitable. Any of these consequences could adversely affect our business, financial condition and results of operations.

Our long-term growth depends, in part, on our ability to develop and enhance our r-SNM System, 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 develop and enhance our r-SNM System. We intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System. Our goals include extending the time between recharging sessions to once a month, introducing features that would enable us to connect our INS to an already implanted InterStim II lead, and expanding the suite of product solutions available for SNM therapy over time. Additionally, we intend to pursue regulatory approval for other indications in the United States in the future.

Developing enhancements to our r-SNM System can be expensive and time-consuming and could divert management's attention away from the commercialization of our r-SNM System and divert financial resources from other operations. The success of any new product enhancements, including approval of our r-SNM System for additional indications, 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 r-SNM System, including additional indications, with data from preclinical studies and clinical studies;
- obtain, and obtain in a timely manner, the necessary regulatory clearances or approvals for new enhancements to our r-SNM System, product modifications or expanded indications for our r-SNM System;
- avoid infringing upon the intellectual property rights of third-parties;
- be fully FDA-compliant with marketing of new devices or modified products;
- competitive counter moves advanced by Medtronic to secure and maintain customers;
- develop an effective and dedicated sales and marketing team to provide adequate education and training to potential users of our r-SNM System; and
- receive adequate coverage and reimbursement for procedures performed with our r-SNM System.

If we are not successful in commercializing our r-SNM System, expanding the indications for which it may be approved and developing and commercializing new product enhancements, our ability to achieve and maintain market share and increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

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. As of December 31, 2018, we had 87 employees. We expect to hire and train new personnel as we continue to grow and expand our operations. Primarily, we plan to build a specialized and dedicated direct sales organization. We are in the process of hiring a specialty sales force of approximately 100 sales professionals, regional sales managers and clinical specialists in advance of the anticipated commercial launch of our r-SNM System in the United States. In addition, we plan to expand our current sales team into select international markets. However, we may not be able to hire a sufficient number of sales representatives to support our U.S. commercial operations in time for commercial launch or at all. Further, we expect to grow our sales force over time. Any failure by us to manage our growth effectively, or to hire a sufficient number of sales representatives, could have an adverse effect on our ability to achieve our development and commercialization goals.

To achieve our revenue goals, we must successfully increase manufacturing output to meet expected customer demand. In the future, we may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate our

revenue. Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth we will need to continue to improve our operational, 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.

In addition, as a public company, we will need to support managerial, operational, financial and other resources to manage our operations, commercialize our r-SNM System and continue our research and development activities. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth, and this growth may place significant strain on us as we grow. Successful growth will also be dependent upon our ability to implement appropriate financial and management controls. Due to our limited experience in managing a company with anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert the attention of our management and business development resources. If we fail to manage these challenges effectively, there may be an adverse effect on our business, financial condition and results of operations.

If the quality of our r-SNM System 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 r-SNM System, including defects in third-party components included in our r-SNM System. 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 r-SNM System does not meet the expectations of physicians or patients. For example, the anticipated battery life of our r-SNM System will vary based on usage and therapy settings. The battery is designed to last for approximately 15 years, but it may be shorter if a patient's required therapy results in the device being used in excess of normal use conditions or if other physical battery failures occur. If the quality of our r-SNM System does not meet the expectations of physicians or patients, then our brand and reputation with those physicians or patients, and our business, financial condition and results of operations, could be adversely affected.

The size and future growth in the market for SNM therapy has 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, including the number of people in the United States and Europe who suffer from symptoms of either OAB or FI and who are readily treatable with and eligible candidates for SNM therapy, is 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 SNM therapy and our belief that the incidence of OAB and FI 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 SNM therapy and our r-SNM System, 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 OAB and FI who are readily treatable with and eligible candidates for SNM therapy, and the actual demand for our r-SNM System 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 r-SNM System may prove to be incorrect. If the actual number of people with OAB and FI who would benefit from our r-SNM System and the size and future growth in the market for our r-SNM System is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business. Additionally, while we have regulatory approvals in Europe, Canada, and Australia for OAB, FI, and UR, we initially intend to pursue regulatory approval in the United States for UUI, a predominant OAB subtype, and we intend to seek regulatory approval for other indications in the United States in the future.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or product improvements or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop new products or product improvements and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or viable product improvements or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could harm our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management’s attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience;

- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and
- unanticipated or undisclosed liabilities of any target.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Potential complications from our r-SNM System or future enhancements to our r-SNM System may not be revealed by our clinical experience.

Based on our experience, complications from use of our r-SNM System may include infection, pain at site, lead migration or fracture, and the body's rejection of the implant. However, if unanticipated side-effects result from the use of our r-SNM System, 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 battery for our r-SNM System is designed to last approximately 15 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 15-year life, physicians and patients may lose confidence in our r-SNM System, which may materially harm our reputation and our business.

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit manufacturing cost of our r-SNM therapy.

Currently, the gross profit generated from the sale of our r-SNM System is not sufficient to cover our operating expenses. To achieve our operating and strategic goals, we need to, among other things, reduce the per unit manufacturing cost of our r-SNM System. This cannot be achieved without increasing the volume of components that we purchase in order to take advantage of volume-based pricing discounts, improve manufacturing efficiency or increase our volume to leverage manufacturing overhead costs. If we are unable to improve manufacturing efficiency and reduce manufacturing overhead costs per unit, our ability to achieve profitability will be severely constrained. Any increase in manufacturing volumes is dependent upon a corresponding increase in sales. The occurrence of one or more factors that negatively impact the manufacturing or sales of our r-SNM System or reduce our manufacturing efficiency may prevent us from achieving our desired reduction in manufacturing costs, which would negatively affect our operating results and may prevent us from attaining profitability.

If we fail to receive access to hospital facilities, our sales may decrease.

In the United States, in order for physicians to use our r-SNM System, 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 require extensive negotiations and management time. In the European Union, or 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.

Our indebtedness to Silicon Valley Bank may limit our flexibility in operating our business and adversely affect our financial health and competitive position, and all of our obligations to Silicon Valley Bank are secured by substantially all of our assets, excluding our intellectual property assets. If we default on these obligations, Silicon Valley Bank could foreclose on our assets.

In February 2018, we entered into a Loan and Security Agreement with Silicon Valley Bank providing for a term loan (the "Term Loan"). In October 2018, we and Silicon Valley Bank entered into an amendment to the Loan and Security Agreement (as so amended, the "Loan Agreement"). Pursuant to the Loan Agreement, we have drawn $20.0 million in three tranches of term loans, with such drawn obligations maturing on December 1, 2021.

The Loan Agreement provides for monthly interest payments through December 31, 2019. On the first day of the end of the interest only period, we will be required to repay the Term Loan in equal monthly installments of principal plus interest through maturity. Outstanding principal balances under the Term Loan bear interest at the prime rate plus 1.75%.

We may prepay amounts outstanding under the Term Loan in increments of $5.0 million at any time with 30 days prior written notice to Silicon Valley Bank. However, all prepayments of the Term Loan prior to maturity, whether voluntary or mandatory (acceleration or otherwise), are also subject to the payment of a prepayment fee equal to (i) for a prepayment made on or after the closing date through and including the first anniversary of the closing date, 3.00% of the principal amount of the Term Loan being prepaid, (ii) for a prepayment made after the date which is the first anniversary of the closing date through and including the second anniversary of the closing date, 2.00% of the principal amount of the Term Loan being prepaid, and (iii) for a prepayment made after the date which is the second anniversary of the closing date and before the maturity date, 1.00% of the principal amount of the Term Loan being prepaid. Additionally, on the earliest to occur of (i) the maturity date of the Term Loan, (ii) the acceleration of the Term Loan, or (iii) the prepayment of the Term Loan, we will be required to make a final payment equal to the original principal amount of such Tranche multiplied by 7.50%. We are currently accruing the portion of the final payment calculated based on the amount outstanding under the Term Loan.

All obligations under the Term Loan are secured by a first priority lien on substantially all of our assets, excluding intellectual property assets and more than 65% of the shares of voting capital stock of any of our foreign subsidiaries. We have agreed with Silicon Valley Bank not to encumber our intellectual property assets without its prior written consent unless a security interest in the underlying intellectual property is necessary to have a security interest in the accounts and proceeds that are part of the assets securing the Term Loan, in which case our intellectual property shall automatically be included within the assets securing the Term Loan. As a result, if we default on any of our obligations under the Loan Agreement, Silicon Valley Bank could foreclose on its security interest and liquidate some or all of the collateral, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. Our business may not be able to generate sufficient cash flow from operations, and future borrowings or other financings may not be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This could place us at a competitive disadvantage compared to our competitors that have less indebtedness.

The Loan Agreement contains certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interest. Subject to certain limited exceptions, these covenants limit our ability to or prohibit us to permit any of our subsidiaries to, as applicable, among other things:

- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of our capital stock;
- convey, sell, lease, transfer, assign, or otherwise dispose of all or any part of our business or property;
- effect certain changes in our business, management, ownership or business locations;
- merge or consolidate with, or acquire all or substantially all of the capital stock or property of any other company;
- create, incur, assume, or be liable for any additional indebtedness, or create, incur, allow, or permit to exist any additional liens;
- make certain investments; and
- enter into transactions with our affiliates.

While we have not previously breached and are currently in compliance with the covenants contained in the Loan Agreement, we may breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, Silicon Valley Bank may choose to declare an event of default and require that we immediately repay all amounts outstanding under the Loan Agreement, terminate any commitment to extend further credit and foreclose on the collateral. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

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

If our r-SNM System is approved in the United States, to ensure adequate inventory supply, we must forecast inventory needs and place orders with suppliers based on our estimates of future demand for our r-SNM System. If approved in the United States, we anticipate there will be an increased demand for our r-SNM System, and our limited historical experience in foreign markets may not provide us with enough data to accurately predict future demand. Our ability to accurately forecast demand for our r-SNM System 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 r-SNM System 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 r-SNM System, 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 r-SNM System and our results of operations.

We rely on third parties for the manufacture of our r-SNM System. This reliance on third parties increases the risk that we will not have sufficient quantities of our r-SNM System 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 r-SNM System. 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 r-SNM System 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 r-SNM System according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our r-SNM System or otherwise do not satisfactorily perform according to the terms of the agreements and/or purchase orders between us and them;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- supplier demands for significant cost increases;
- the possible breach by the third-party manufacturers of our agreements with them;
- the failure of third-party manufacture to comply with applicable regulatory requirements;

- the possible failure of the third-party to manufacture such component of our r-SNM System according to our specifications; and
- the possible misappropriation 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 r-SNM System. 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. 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 develop, obtain marketing approval for or market our r-SNM System. 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.

Any performance failure on the part of our existing or future manufacturers could delay marketing approval. We do not currently have arrangements in place for redundant supply of certain components of our r-SNM System. If our current third-party manufacturers cannot perform as agreed, we may be required to replace those manufacturers. 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.

Our current and anticipated future dependence upon others for the manufacture of our r-SNM System may adversely affect our future profit margins and our ability to commercialize our r-SNM System on a timely and competitive basis.

We have a limited history of manufacturing and assembling our r-SNM System in commercial quantities and may encounter related problems or delays that could result in lost revenue.

The manufacturing process of our r-SNM System 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 r-SNM System and, as a result, we may have difficulty manufacturing and assembling this system in sufficient quantities in a timely manner. To manage our manufacturing and operations with our suppliers, we will need to forecast anticipated product orders and material requirements to predict our inventory needs from six months to a year in advance and enter into purchase orders on the basis of these requirements. 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 r-SNM System on our expected timeline. As a result of this or any other delays, we may encounter difficulties in production of our r-SNM System, including problems with quality control and assurance, component supply shortages or surpluses (including with respect to the ceramic and titanium we use in our r-SNM System), increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements.

Performance issues, service interruptions or price increases by shipping carriers could adversely affect our business and harm our reputation and ability to provide our r-SNM System on a timely basis.

Expedited, reliable shipping will be essential to our operations. We intend to rely heavily on providers of transport services for reliable and secure point-to-point transport of our r-SNM System to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of our r-SNM System, it would be costly to replace our r-SNM System in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our r-SNM System 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 r-SNM System on a timely basis.

Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. 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 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. It is not always possible to identify and deter misconduct by our employees, consultants and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to 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 r-SNM System at prices necessary to support our current business strategies.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payors. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for price 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, or 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 r-SNM System.

To successfully market and sell our r-SNM System 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 currently have a limited sales and marketing organization outside the United States. We expect to have sales and operations both inside and outside the United States. Our strategy is to increase our international presence in Europe, Canada, and Australia that have established and favorable reimbursement. International sales and operations are subject to a number of risks, including:

- difficulties in staffing and managing our international sales, marketing, and other operations;
- increased competition as a result of more products and procedures receiving regulatory approval or otherwise being free to market in internationally;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;

- reduced or varied protection for intellectual property rights in some countries;
- export restrictions, trade regulations, and foreign tax laws;
- fluctuations in foreign currency exchange rates;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- customs clearance and shipping delays;
- political, social, and economic instability internationally, terrorist attacks, and security concerns in general;
- 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
- FCPA, OFAC, the Bribery Act, each of which is defined below, and other export control, anti-corruption, anti-money laundering and anti-terrorism laws and regulations.

If one or more of these risks are realized, our ability to expand our operations into international markets could be limited, which could adversely affect our business, financial condition and results of operations.

Our ability to maintain our competitive position will depend on our ability to retain senior management and other highly qualified personnel.

Our success will depend in part on our continued ability to 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 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.

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, particularly after the expiration of the lock-up agreements entered into in connection with our IPO. Replacement of any employees who leave our company could 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.

If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our r-SNM System, 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 expect to derive nearly all of our revenue from the sale of our r-SNM System 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 r-SNM System 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 r-SNM System and the related procedures because they may determine that our r-SNM System 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. In addition, although 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, however this process may not result in positive coverage determination for these patients. Further, any decline in the amount payors are willing to reimburse our target customers could make it difficult for our target customers to adopt or continue using our r-SNM System and could create additional pricing pressure for us. If we are forced to lower the price we charge for our r-SNM System, 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.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. Coverage and reimbursement for procedures using our r-SNM System can differ significantly from payor to payor. Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. Third-party payor policies may not provide coverage for procedures in which our r-SNM System is used.

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. Some countries or regions may require us to gather additional clinical data before granting coverage and reimbursement for our r-SNM System. 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 r-SNM System is designed to affect, and any future enhancements to our r-SNM System will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our r-SNM System 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 r-SNM System causes, or merely appears 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 r-SNM System, 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 r-SNM System and develop enhancements to our r-SNM System;
- decreased demand for our r-SNM System;
- 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 r-SNM System 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 r-SNM System, 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 r-SNM System.

We bear the risk of warranty claims on our r-SNM System. 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.

Unfavorable global economic conditions could adversely affect our business, financial condition or result of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including weakened demand for our r-SNM System, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business.

Failure of a key information technology system, process, or site could have an adverse effect on our business.

We rely extensively on information technology systems to conduct our business. These systems affect, among other things, ordering and managing materials from suppliers, shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security, and other processes necessary to manage our business. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate on a timely basis, we may experience interruptions in our operations, which could have an adverse effect on our business. Furthermore, any breach in our information technology systems could lead to the unauthorized access, disclosure and use of non-public information, including information from our patient registry or other patient information, which is protected by HIPAA, as defined below, and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation.

If our facilities are damaged or become inoperable, we will be unable to continue to research and develop our r-SNM System 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 in a single location 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, tornadoes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

Our results may be impacted by changes in foreign currency exchange rates.

If our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could expose us to foreign currency risks, including changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business could be harmed.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, 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 U.S. Foreign Corrupt Practices Act, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the U.K. Bribery Act of 2010, or 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 are in the process of implementing 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, or 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, or 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.

U.S. federal income tax reform could adversely affect us or our stockholders.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the TCJA, was signed into law, significantly reforming the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a territorial system and modifies or repeals many business deductions and credits. We continue to examine the impact the TCJA may have on our business. We are in the process of evaluating the effect of the TCJA on our projection of minimal cash taxes or to our net operating losses. The estimated impact of the TCJA is based on our management's current knowledge and assumptions and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. The impact of the TCJA on holders of our common stock remains uncertain and could be adverse. There remains significant uncertainty as to the impact of the TCJA on us and on any investment in our common stock.

Risks Related to Government Regulation

Our r-SNM System and 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 and our r-SNM System are subject to extensive, complex, costly and evolving regulation in the United States, 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, pre-market 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 r-SNM System 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 r-SNM System, and in the most serious cases, criminal penalties.

In the event our r-SNM System receives regulatory approval in the United States, we will remain subject to the periodic scheduled or unscheduled inspection of our facilities, review of production processes, and testing of our r-SNM System 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.

If we experience delays in obtaining approval or if we fail to obtain approval of our r-SNM System or expanded indications, the commercial prospects for our r-SNM System may be harmed and our ability to generate revenue will be materially impaired.

We may not receive the necessary clearances or approvals for our r-SNM System or expanded indications, and failure to timely obtain necessary clearances or approvals for our r-SNM System or expanded indications would adversely affect our ability to grow our business.

As an active-implantable device, our r-SNM System is 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, which is required for our r-SNM System, 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, if we were to pursue regulatory approvals for additional indications for our r-SNM System, we would be required to conduct additional clinical studies or pre-clinical studies to support such indications, which would be time-consuming and expensive, and may produce results that do not support such regulatory approvals.

Modifications to products that are approved through a PMA application generally require FDA approval. In addition, a PMA generally requires the performance of one or more clinical studies. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Typically, the PMA review process can take from six to 18 months, with the duration depending on a variety of factors.

In 2016, our r-SNM System received regulatory approval in Europe and Canada, and in 2018 in Australia, for the treatment of OAB, FI, and UR. We have not obtained regulatory approval of our r-SNM System in the United States. In 2017, the FDA granted us an IDE allowing us to conduct a pivotal study designed to demonstrate the safety and effectiveness of our r-SNM System for the treatment of UUI in order to obtain FDA approval in the United States through the PMA pathway. Any delay or failure to obtain necessary regulatory approvals for our r-SNM System could harm our business. Furthermore, even if we are granted regulatory approvals, they may include significant limitations on the indicated use for our r-SNM System, which may limit the market for the device.

If our r-SNM System is approved in the United States through the PMA pathway, any modification to or additional indications for our r-SNM System 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, generate additional data to submit to the FDA or additional indications for approved products than we had expected, 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:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our r-SNM System 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 our clinical studies or the interpretation of data from pre-clinical studies or clinical studies;
- serious and unexpected adverse device effects experienced by participants in our clinical studies;
- the data from our pre-clinical studies and clinical studies may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use 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 our clinical data or regulatory filings insufficient for clearance or approval.

For example, as part of the IDE approval process for our ARTISAN-SNM pivotal study, the FDA recommended that we should make several modifications to the study design in order for the study to serve as the primary clinical support for a future marketing approval. Specifically, despite our responses and supporting documentation that we submitted in support of our study design, the FDA reiterated its previously expressed recommendations that we make the following modifications to our ARTISAN-SNM pivotal study:

- exclude patients with MUI;
- use either a seven-day bladder diary or two separate three-day bladder diaries;
- use a 12-month primary effectiveness endpoint in order to account for the placebo effect and enable assessment of durability of the treatment effect;
- use all patients in whom an implant is attempted, not initial responders after one month, for primary efficacy analysis;
- use multiple imputation to account for missing primary endpoint data;
- revise the protocol to include details on statistical analysis methods for analyzing the primary and secondary endpoints, analysis population, method for handling missing endpoint data and sensitivities and poolability analyses;
- use a two-sided 95% confidence interval; and
- provide further justification for restarting with a new activation date after a lead issue.

In response, we engaged with the FDA regarding its recommendation, including our latest IDE supplement, which we submitted to the FDA in September 2018 to address certain of its recommendations. As a result, we incorporated a number of recommended study modifications. However, to date we elected not to incorporate several of the recommended modifications based on what we believe are currently accepted urology practice guidelines and the design of previous OAB clinical studies accepted by the FDA. We believe certain of these modifications would have resulted in a study design that increased study site and patient burdens, decreased the feasibility of enrollment or were not clearly supported by available peer-reviewed literature or currently accepted urology practice guidelines. At this point in the study, some of the FDA's recommendations cannot be implemented. For example, we cannot exclude patients with MUI and we cannot change the three-day bladder diaries taken at baseline to seven-day bladder diaries. On October 19, 2018, the FDA approved our latest IDE supplement and removed certain of its prior study design recommendations while reiterating several others. On November 9, 2018, we filed an additional IDE supplement with the FDA regarding certain of its reiterated recommendations, and the response from the FDA is pending.

We completed enrollment of patients for the ARTISAN-SNM study in June of 2018. The approved protocol from the FDA based on our September 2018 IDE supplement incorporated certain of the FDA's recommended study design considerations. Although we have not modified the ARTISAN-SNM pivotal study design to address all of the considerations that the FDA has reiterated, based on the study results to date, we believe we will be able to satisfy the FDA with reasonable assurance of the safety and effectiveness of our r-SNM system to support its marketing approval. However, it is possible that the FDA may not consider the results to be sufficiently strong or that, in part due to its concerns with our study design, the FDA will not accept the data as a reasonable assurance of safety and effectiveness, which would materially and adversely affect our ability to obtain marketing approval of our r-SNM System. If we intend to modify the study design to address any of the above FDA considerations that we have not already addressed, we will be required to obtain FDA approval of an IDE supplement before implementing the changes, which could result in significant delays. The approval requirements for an IDE supplement are generally the same as an original IDE, and they are approved if the FDA does not object within 30 days. We would also be required to get IRB approval of the protocol changes if the changes involve the rights, safety, or welfare of the patients, and some investigators may determine that local rules require additional approvals from a local IRB.

In addition, incorporating modifications may be costly or not possible at this point in the ongoing clinical study or lead to delays in obtaining approval from the FDA, which may be significant and adversely and materially

affect our ability to successfully commercialize our r-SNM System. Further, even if we make changes to the study design to address these considerations, the FDA may not approve our r-SNM System.

We initially submitted a literature-based PMA on January 9, 2018, in which we claimed equivalence to InterStim II based on the review of technical specifications, published clinical studies, and other information. On May 9, 2018, the FDA responded to our initial literature-based PMA and requested that we submit additional information to demonstrate that our r-SNM System is sufficiently similar to InterStim II, as well as asking us to address a number of other matters. On October 18, 2018, we responded to the FDA and withdrew our initial literature-based PMA. On December 3, 2018, we submitted a new literature-based PMA claiming equivalence to InterStim II. This literature-based PMA was based on reasonable safety and effectiveness data from a literature review. In this PMA filing, we submitted existing literature reporting on InterStim II. In addition to the technical specifications, testing data and published literature, we included one-year follow-up data from our 51-patient RELAX-OAB European post-market clinical follow-up study to support the PMA, and subsequently provided the FDA with the clinical results on the first 60 patients to reach their six-month primary endpoint from our ARTISAN-SNM pivotal study. This PMA filing incorporates all elements of the r-SNM System, the External Trial System, and related accessories, as well as the additional information addressing FDA's questions in its May 9, 2018 correspondence. Since the PMA submission on December 3, 2018, we have submitted various amendments to the PMA. These amendments include data in support of conditional full-body MRI labeling, and complete three-month and six-month clinical data from the ARTISAN-SNM study.

In addition to this, on March 1, 2019, we submitted a new literature-based PMA seeking approval for FI. This PMA is also based on an existing literature review of Interstim II.

The FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our r-SNM System or impact our ability to modify or seek additional indications for our r-SNM System 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. For example, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, and the FDA Reauthorization Act, enacted in 2017, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. Some of these proposals and reforms could impose additional regulatory 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 r-SNM System in member countries of the European Economic Area, or EEA (which is composed of the 28 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), or 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 by a Notifiable Body that this is the case is a prerequisite to be able to affix the Conformité Européene, or CE, mark to our r-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 r-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 r-SNM System, 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 r-SNM System or our external trial system, which would prevent us from selling it within the EEA.

Modifications to our r-SNM System may require us to obtain new PMA approvals or approvals of a PMA supplement, and if we market modified products without obtaining necessary approvals, we may be required to cease marketing or recall the modified products until required approvals are obtained.

Certain modifications to a PMA-approved device may require approval of a new PMA or a PMA supplement, or alternatively a notification or other submission to FDA. We will be responsible for deciding whether a modification requires approval by the FDA. However, the FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our r-SNM System that we believe do not require approval of a new PMA or PMA supplement. If the FDA disagrees with our determination and requires us to submit a new PMA or PMA supplement for modifications to previously approved products, we may be required to cease marketing or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. Any delay or failure in obtaining required approvals would adversely affect our ability to introduce enhanced products in a timely manner, which in turn would harm our future growth.

The misuse or off-label use of our r-SNM System, if approved by the FDA, 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 r-SNM System, if approved by the FDA. 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. If we receive approval for our r-SNM System in the United States for the treatment of OAB and UR, or FI, physicians could use our r-SNM System on their patients in a manner that is inconsistent with the approved label, including the treatment of other indications. If approved, we will train our marketing personnel and sales representatives to not promote our r-SNM System for uses outside of FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our r-SNM System 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 r-SNM System off-label. Furthermore, the use of our r-SNM System 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. In addition, physicians have experience using the Medtronic system, which is approved for several indications, including UUI, UUF, FI, and UR. If physicians adopt our r-SNM System, for which we have not pursued regulatory approval in the United States for indications other than for the treatment of OAB, UR, and FI, physicians could use our r-SNM System off-label for additional unapproved indications based in part on their familiarity with the Medtronic system.

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 r-SNM System 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 r-SNM System is approved, and subsequently misused or used with improper techniques or is determined to cause or contribute to patient harm, we may become subject to costly litigation by our customers or patients. Product liability claims could divert management's attention from the commercialization of our r-SNM System, be expensive to defend, result in sizeable damage awards against us that may not be covered by insurance, and subject us to negative publicity resulting in reduced sales of our r-SNM System.

The clinical study process required to obtain regulatory approvals is lengthy and expensive with uncertain outcomes. If clinical studies of our r-SNM System do not produce results necessary to support regulatory clearance or approval in the United States or elsewhere, we will be unable to gain regulatory approval for, expand the indications for or commercialize our r-SNM System and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of our r-SNM System.

To date, we have not obtained PMA approval for our r-SNM System. In order to obtain PMA approval for a device, 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. Any of our products, including our r-SNM System, could malfunction or produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical studies. We, the FDA, or another regulatory

authority may suspend or terminate clinical studies at any time to avoid exposing trial participants to unacceptable health risks.

We completed enrollment of patients for the ARTISAN-SNM study in June of 2018. The approved protocol from the FDA based on our September 2018 IDE supplement incorporated certain of the FDA's recommended study design considerations. Although we have not modified the ARTISAN-SNM pivotal study design to address all of the considerations that the FDA has reiterated, based on the study results to date, we believe we will be able to satisfy the FDA with reasonable assurance of the safety and effectiveness of our r-SNM system to support its marketing approval. However, it is possible that the FDA may not consider the results to be sufficiently strong or that, in part due to its concerns with our study design, the FDA will not accept the data as a reasonable assurance of safety and effectiveness, which would materially and adversely affect our ability to obtain marketing approval of our r-SNM System. If we intend to modify the study design to address any of the above FDA considerations that we have not already addressed, we will be required to obtain FDA approval of an IDE supplement before implementing the changes, which could result in significant delays. The approval requirements for an IDE supplement are generally the same as an original IDE, and they are approved if the FDA does not object within 30 days. We would also be required to get IRB approval of the protocol changes if the changes involve the rights, safety, or welfare of the patients, and some investigators may determine that local rules require additional approvals from a local IRB.

In addition, incorporating modifications may be costly or not possible at this point in the ongoing clinical study or lead to delays in obtaining approval from the FDA, which may be significant and adversely and materially affect our ability to successfully commercialize our r-SNM System. Further, even if we make changes to the study design to address these considerations, the FDA may not approve our r-SNM System.

We initially submitted a literature-based PMA on January 9, 2018, in which we claimed equivalence to InterStim II based on the review of technical specifications, published clinical studies, and other information. On May 9, 2018, the FDA responded to our initial literature-based PMA and requested that we submit additional information to demonstrate that our r-SNM System is sufficiently similar to InterStim II, as well as asking us to address a number of other matters. On October 18, 2018, we responded to the FDA and withdrew our initial literature-based PMA. On December 3, 2018, we submitted a new literature-based PMA claiming equivalence to InterStim II. This literature-based PMA was based on reasonable safety and effectiveness data from a literature review. In this PMA filing, we submitted existing literature reporting on InterStim II. In addition to the technical specifications, testing data and published literature, we included one-year follow-up data from our 51-patient RELAX-OAB European post-market clinical follow-up study to support the PMA, and subsequently provided the FDA with the clinical results on the first 60 patients to reach their six-month primary endpoint from our ARTISAN-SNM pivotal study. This PMA filing incorporates all elements of the r-SNM System, the External Trial System, and related accessories, as well as the additional information addressing FDA's questions in its May 9, 2018 correspondence. Since the PMA submission on December 3, 2018, we have submitted various amendments to the PMA. These amendments include data in support of conditional full-body MRI labeling, and complete three-month and six-month clinical data from the ARTISAN-SNM study.

In addition to this, on March 1, 2019, we submitted a new literature-based PMA seeking approval for FI. This PMA is also based on an existing literature review of Interstim II.

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, which could further delay the clearance or approval of our r-SNM System. The data we collect from our pre-clinical studies and clinical studies may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and effectiveness of our r-SNM System in our clinical studies, we will be unable to obtain regulatory clearance or approval to market our r-SNM System.

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. We may not meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our r-SNM System may be delayed and, as a result, our stock price may decline.

Clinical studies are necessary to support PMA applications and may be necessary to support PMA supplements for modified versions of, or additional indications for, our r-SNM System. 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 approval of a PMA. We will likely need to conduct additional clinical studies in the future to support new indications for our r-SNM System or for approvals or clearances, or for the approval of the use of our r-SNM System 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;
- we may not reach agreements with prospective contract research organizations, or 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;
- regulators or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- 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 r-SNM System 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. For example, patients may be discouraged from enrolling in our clinical studies if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of a product, or they may be persuaded to participate in contemporaneous clinical studies of a competitor's product. In addition, patients participating in our clinical studies may drop out before completion of the trial or experience adverse medical events unrelated to our r-SNM System. 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, or 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 our r-SNM System or any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of the product or indication for use. Even if our r-SNM System is cleared or approved in the United States, commercialization of our r-SNM System in foreign countries requires approval by regulatory authorities in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical studies. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

If our r-SNM System is approved by the FDA, failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw our r-SNM System from the market.

If we obtain FDA approval for our r-SNM System, we will be 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 r-SNM System. For example, if our r-SNM System is approved, we will be 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.

In addition, in order to obtain PMA approval for our r-SNM System, we may be to subject to several conditions of approval, including a post-market long-term study and extended follow-up of the pre-market study cohort. Any

failure to comply with the conditions of approval could result in the failure to obtain PMA approval or delay or withdrawal of PMA approval and the inability to market the device. Failure to conduct the required studies in accordance with IRB and informed consent requirements, or adverse findings in these studies, could also be grounds for failure to obtain PMA approval or delay or withdrawal of PMA approval.

Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even if we obtain the proper regulatory approval to market our r-SNM System, we will 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 r-SNM System;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our request for PMA approval of our r-SNM System and any 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 r-SNM System;
- 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 r-SNM System 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 r-SNM System or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our r-SNM System must comply with the FDA's Quality System Regulation, or 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 r-SNM System will also be 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 r-SNM System, if approved. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with the manufacturing processes for our r-SNM System 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 r-SNM System, 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 for our product, clinical holds, refusal to permit the import or export of our r-SNM System, and criminal prosecution of us or our employees. Any of these actions could significantly and negatively affect supply of our r-SNM System. 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 our r-SNM System is approved by the FDA and treatment guidelines for the indications for which it is approved later change or the standard of care evolves, we may need to redesign and seek a new marketing authorization from the FDA for our r-SNM System.

If our r-SNM System is approved by the FDA and treatment guidelines for the indications for which it is approved change or the standard of care evolves, we may need to redesign our r-SNM System, 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 r-SNM System could be diminished and our business could be adversely affected.

If approved, our r-SNM System 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. The discovery of serious safety issues with our r-SNM System, or a recall of our r-SNM System, either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

If our r-SNM System is approved by the FDA, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which will require us to report to the FDA when we receive or become aware of information that reasonably suggests that our r-SNM System 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 r-SNM System or delay in clearance or approval of modifications to our r-SNM System.

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 r-SNM System could cause serious injury or death. We may also choose to voluntarily recall our r-SNM System 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 r-SNM System 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 r-SNM System 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 r-SNM System, 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 r-SNM System 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 r-SNM System after obtaining regulatory approval in the United States or other jurisdictions, 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 r-SNM System and could substantially increase the costs of commercializing our r-SNM System. The demand for our r-SNM System could also be negatively impacted by any adverse effects of a competitor's product or treatment.

If we do not obtain and maintain international regulatory registrations or approvals for our r-SNM System, we will be unable to market and sell our r-SNM System outside of the United States.

We currently have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR. We may in the future seek marketing approvals in additional countries but do not have current plans to do so. Sales of our r-SNM System outside of the United States will be subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our r-SNM System, or only require notification, others require that we obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining additional registrations or approvals, can be expensive and time-consuming, and we may not receive regulatory approvals in each country in which we plan to market our r-SNM System or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our r-SNM System, we may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory approval by the FDA does not ensure registration, clearance or approval by regulatory authorities in other countries, and registration, clearance or approval by one or more foreign regulatory authorities does not ensure registration, clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

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 our r-SNM System, or to manufacture, market or distribute our r-SNM System after clearance or approval is obtained.

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 our r-SNM System. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of or make it more difficult to obtain approval for, manufacture, market or distribute our r-SNM System. 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.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. The Medical Devices Regulations would be directly applicable and are intended to eliminate current differences in the regulation of medical devices among EEA member states. 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.

The Medical Devices Regulation will only become applicable after the three-year transition period ends on May 26, 2020. Up until this date, conformity certificates can continue to be issued validly by Notifiable Bodies under the AIMD and Medical Devices Directives. Alternatively, during the three-year transition period, manufacturers can choose to conform with and have their products certified under the Medical Devices Regulations. Certificates of compliance issued pursuant to these Directives prior to May 26, 2020 will continue to be valid for up to a period of four years. However, after May 26, 2020, new products placed on the market may only be certified under the Medical Device Regulations regime. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we conduct our business in the EEA.

In addition, the withdrawal of the United Kingdom from the EU, or Brexit, will take effect either on the effective date of the withdrawal agreement or, in the absence of an agreement, two years after the United Kingdom provided its notice of withdrawal. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to EU markets either during a transitional period or more permanently. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the referendum could materially change the regulatory regime applicable to products approved and sold in the United Kingdom. It is possible that there will be greater restrictions on imports and exports between the United Kingdom and EU countries, increased regulatory complexities, and economic and political uncertainty in the region. Because of the continued uncertainty about the effects, implementation, or potential repeal of Brexit, we cannot quantify or predict with any certainty the likely impact of Brexit or related legislation on our business, financial condition, and results of operations.

Furthermore, Brexit could adversely affect European and worldwide economic or market conditions and could contribute to instability in global financial markets. Brexit is likely to lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which EU laws to replace or replicate. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, financial condition, and results of operations.

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. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $74,792 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including 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. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- 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;

- the Health Insurance Portability and Accountability Act of 1996, or 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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- 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 require certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, or CHIP, to report annually to the DHHS Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties of $11,052 per failure up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or 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. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state;

- 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, foreign and state laws, including the EU General Data Protection Regulation, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; 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 r-SNM System. 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. In addition, these rules are constantly under scrutiny. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme was declared invalid. In July 2016 the European Commission adopted the U.S.-EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this framework is under review and there is currently litigation challenging other EU mechanisms for adequate data transfers (i.e., the standard contractual clauses). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our EU business to the U.S., and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the EU General Data Protection Regulation 2016/679, or the GDPR, which came into effect on May 25, 2018, as well as current challenges to these mechanisms in the European courts.

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.

The laws in the EU are under constant reform. Since May 25, 2018, we have been subject to the requirements of the GDPR because we are processing personal data in the EU and/or offering goods to, or monitoring the behavior of, individuals in the EU. The GDPR implements more stringent administrative requirements for controllers and processors of personal data, including, for example, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data, additional obligations when we contract with service providers, and more robust rights for individuals over their personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. If we do not comply with our obligations under the GDPR, we could be exposed to significant fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher.

Our failure to obtain necessary U.S. Federal Communications Commission, or FCC, authorizations, and comply with applicable FCC regulations, could impair our ability to commercialize our r-SNM System in the United States.

Because our r-SNM System includes a wireless radio frequency transmitter and receiver, it is subject to equipment authorization requirements in the United States. The FCC requires advance clearance of all radio frequency devices before they can be imported, 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. We intend to submit an equipment certification application for non-experimental use to the FCC for our r-SNM System. Our r-SNM System has not received FCC approval for non-experimental use, and it could take several months to receive such approval. If FCC approval is obtained, it will be based on the current system design and specifications. Any modifications to our r-SNM System may require new or further FCC approval before we are permitted to market and sell a modified system, and it could take several months to obtain such new or modified approval. FCC approval has no impact on whether we will receive PMA approval.

In addition, applicable FCC requirements will restrict us to a particular band of frequencies for transmitting data in support of specific diagnostic or therapeutic functions. Failure to comply with all applicable restrictions on the use of such frequencies, or unforeseeable difficulties with the use of such frequencies, could impede our ability to

commercialize our r-SNM System and could subject us to fines, penalties and other sanctions. In addition, any change to our transmission frequency following receipt of FCC approval may require us to obtain additional, or modified, regulatory approvals, which would be costly and time-consuming.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020;

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;

- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and

- expanded the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the Affordable Care Act will have on our business. The taxes imposed by the Affordable Care Act and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our r-SNM System, and/or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition and results of operations. The federal government may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the TCJA was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our r-SNM System, or additional pricing pressure, and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our r-SNM System, which in turn could impact our ability to successfully commercialize our r-SNM System and could 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 r-SNM System 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, or 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 r-SNM System. The cost of compliance with the rule could adversely affect our results of operations.

Risks Related to Intellectual Property

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. 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 r-SNM System and defend it against competitors.

We own numerous issued patents and pending patent applications that relate to our r-SNM System and several issued patents and patent applications were licensed from AMF in 2013 pursuant to the License Agreement. As of December 31, 2018, we wholly owned 19 issued U.S. patents and 22 issued foreign patents, and 15 pending U.S. patent applications and 57 pending foreign patent applications. We also license from AMF 30 issued U.S. patents and four

pending U.S. patent applications, as well as 41 issued foreign patents and 25 pending foreign patent applications. Issued patents owned or used by us will expire between 2023 and 2037.

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 r-SNM System, or any additional features we develop for our r-SNM System or any new products. Other parties may have developed technologies that may be related to or competitive with our r-SNM System, 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 r-SNM System.

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 r-SNM System 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 r-SNM System are invalidated or found unenforceable, or, if a court found that valid, enforceable patents held by third parties covered our r-SNM System, our competitive position could be harmed, or, we could be required to incur significant expenses to enforce or defend our rights.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- our patents, or our pending patent applications, if issued, will include claims having a scope sufficient to fully protect our r-SNM System;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our r-SNM System on a substantial scale, if approved, before our relevant patents have expired;
- we were the first to make, or file for patent protection of, the inventions covered by each of our patents and pending patent applications, as is dictated by the applicable national patent laws in effect at the time of a patent application being filed;
- we were the first to file patent applications for these inventions, where such rules are applicable;

- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

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 r-SNM System, 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.

Litigation or other proceedings or third-party claims of intellectual property infringement against us 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 r-SNM System, 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 r-SNM System. We do not always conduct independent reviews of patents issued to third parties. 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 r-SNM System 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 r-SNM System 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 r-SNM System 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. If any third-party patents were held by a court of competent jurisdiction to cover our r-SNM System, the holders of any such patents may be able to block our ability to commercialize our product unless we obtain a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

In addition to claims of patent infringement, third parties may bring claims against us, or AMF, asserting misappropriation of proprietary technology or other information in the development, manufacture and commercialization of our r-SNM System. Defense of such a claim would require dedicated time and resources, which time and resources could otherwise be used by us toward the maintenance of our own intellectual property and the development and commercialization of our r-SNM System, or by any of our current or future licensors for operational upkeep and manufacturing of our r-SNM System.

The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney’s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive, or infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms, or at all, or, from third parties whom 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 r-SNM System, 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 r-SNM System 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 r-SNM System, including future technologies, we may have to withdraw our r-SNM System from the market or may be unable to commercialize our r-SNM System.

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 r-SNM System.

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 r-SNM System 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 r-SNM System. 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 r-SNM System, which could have an adverse effect on our business, results of operations and financial condition.

Recent changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act (the "AIA") includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The U.S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA, and in particular, the first to file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if that inventor is not the first to file an application for patenting that invention, even if such inventor was the first to invent such invention. Accordingly, it is not clear what, if any, impact the AIA will have on the operation of our business.

The AIA could also increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the AIA provides that an administrative tribunal known as the Patent Trial and Appeals Board ("PTAB") provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them.

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 r-SNM System, 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 develop or market our r-SNM System. In addition, any claims asserted against us by AMF may be costly and time-consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business.

Risks Related 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:

- announcements of regulatory approval or disapproval of our r-SNM System and any future enhancements to our r-SNM System;
- adverse results from or delays in clinical studies of our r-SNM System;
- unanticipated safety concerns related to the use of our r-SNM System;
- FDA or other U.S. or foreign regulatory or legal actions or changes affecting us or our 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;
- 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 r-SNM System;
- 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 future 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;
- 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;
- 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; 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.

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 equity research analysts publish about us and our business. If one or more of the equity research 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 equity research analysts ceases coverage of our 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.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Based on the beneficial ownership of our common stock as of December 31, 2018, our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, will control approximately 59.9% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of our company, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets, and might affect the prevailing market price of our common stock due to investors’ perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

Future sales of our common stock, or the perception that such sales may occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that these sales may occur, could result in a decrease in the market price of our common stock. 21,269,965 shares of our common stock are currently restricted as a result of securities laws or 180-day lock-up agreements (which may be waived with or without notice by Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC) but will be able to be sold beginning 180 days after October 30, 2018, unless held by one of our affiliates, in which case the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act. We, our directors, executive officers, and substantially all of our other existing equityholders have agreed that, without the prior written consent of the representatives of the underwriters for our IPO, Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC, we and they will not, subject to certain exceptions and extensions, during the period ending 180-days after the date of the final prospectus relating to our IPO, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock or publicly disclose the intention to do any of the foregoing. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC may in their discretion and at any time without notice release all or any portion of the shares of our common stock subject to the lock-up.

In addition, holders of an aggregate of up to 16,701,297 shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. In addition, we have filed a registration

statement with the SEC covering shares of our common stock outstanding under our 2014 Plan and available for future issuance under the 2018 Plan, and may file future registration statements covering shares of our common stock for issuance under any future equity incentive plans. Upon effectiveness of such registration statements, any shares subsequently issued under such plans will be eligible for sale in the public market, except to the extent that they are restricted by the lock-up agreements referred to above and subject to compliance with Rule 144 in the case of our affiliates. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of our common stock.

We have incurred and will continue to incur significant costs as a result of being a public company, which may adversely affect our business, financial condition and results of operations.

We have incurred and will continue to incur significant costs associated with corporate governance requirements that are applicable to us as a public company, including rules and regulations of the SEC, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Exchange Act, as well as the listing requirements ("Nasdaq Marketplace Rules"), of the Nasdaq Global Select Market ("Nasdaq"). These rules and regulations are expected to significantly increase our accounting, legal and financial compliance costs and make some activities more time-consuming. We also expect these rules and regulations to make it more expensive for us to maintain our directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition and results of operations.

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 will need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls when we become subject to this requirement could negatively affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on Nasdaq.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act ("JOBS Act"), depending on whether we choose to rely on certain exemptions set forth in the JOBS Act.

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 the authorized number of directors may be changed only by resolution of our board of directors and that a director may only be removed with or without cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company;

- prohibit cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; and

- provide that special meetings of our stockholders may be called only by the Chair of the board, our Chief Executive Officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, which may delay the ability of our stockholders to force consideration by our 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 (the "DGCL"), which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This provision could have the effect of delaying or preventing a change in control of our 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 or any action asserting a claim that is governed by the internal affairs doctrine, 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. In addition, unless we consent in writing to the selection of an alternative forum, the U.S. District Court for the District of Delaware shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. 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 this provision of our certificate of incorporation. This choice of forum provision 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 this provision 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.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. In addition, pursuant to the Loan Agreement with Silicon Valley Bank, we are prohibited from paying cash dividends without the prior written consent of Silicon Valley Bank and future debt instruments may materially restrict our ability to pay dividends on our common stock. If we do not pay dividends, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We are an "emerging growth company" and a "smaller reporting company" and the reduced reporting requirements available to "emerging growth companies" and "smaller reporting companies" could make our common stock less attractive to investors.

We are an "emerging growth company" and a "smaller reporting company" under the U.S. federal securities laws. For as long as we remain an emerging growth company and/or smaller reporting company, we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not emerging growth companies or smaller reporting companies. These provisions include, but are not limited to:

- being permitted to have only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial condition and results of operations disclosure;
- an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- reduced disclosure about executive compensation arrangements in our periodic reports, registration statements and proxy statements; and
- exemptions from the requirements to seek non-binding advisory votes on executive compensation or golden parachute arrangements.

To the extent we take advantage of any of these exemptions, the information that we provide stockholders may be different than what is available with respect to other public companies.

We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 date before that time, in which case, we would no longer be an emerging growth company as of the following December 31. Even if we do not qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements that are applicable to emerging growth companies.

Investors could find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our trading price may be more volatile.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

In August 2014, we 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 November 2017, we entered into a new lease agreement (the "Lease") with our current landlord, The Irvine Company, LLC, for the lease of approximately 25,548 square feet of office space of a building located in Irvine, California, which serves as our principal executive offices and includes general office, research and development, lab, and manufacturing spaces. We utilize our old currently-leased space through the lease expiration date to conduct the training of our sales team.

Unless earlier terminated, the term of the Lease (the "Initial Term") will expire on the final day of the calendar month following the seventh anniversary of the commencement date. The commencement date was set as August 2018.

For additional information, see Note 4 to the Consolidated Financial Statements in Part II, Item 8 of this Report.

Item 3. Legal Proceedings.

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We currently are not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our results of operations, financial position or cash flows. Regardless of the outcome, any litigation could have an adverse impact on us due to defense and settlement costs, diversion of management resources and other factors.

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 March 1, 2019, there were approximately 47 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. In addition, pursuant to the Loan Agreement with Silicon Valley Bank, we are prohibited from paying cash dividends without the prior written consent of Silicon Valley Bank.

Recent Sales of Unregistered Securities

During 2018, prior to filing our registration statement on Form S-8 in November 2018, we granted stock options and stock awards to employees, directors and consultants under our 2014 Stock Incentive Plan, as amended, covering an aggregate of 570,180 shares of common stock, at a weighted average exercise price of $1.62 per share. No options granted in 2018 were canceled without being exercised.

Additionally, during 2018, we sold an aggregate of 55,840 shares of common stock to employees, directors and consultants for consideration in the aggregate amount of $0.1 million upon the exercise of stock options and stock awards.

We issued the above-described securities in reliance upon exemptions from registration under the Securities Act for the sales and issuances of securities under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Initial Public Offering

Use of Proceeds

On October 30, 2018, our Registration Statement on Form S-1 (File No. 333-227732) relating to our IPO was declared effective by the SEC. On November 2, 2018, we completed our IPO, pursuant to which we sold an aggregate of 9,200,000 shares of our common stock, at a public offering price of $15.00 per share, for aggregate gross proceeds of $138.0 million. We received net proceeds of approximately $126.0 million, net of $9.7 million of underwriting discounts and commissions and $2.3 million of offering expenses paid or payable by us. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC acted as joint book-running managers for the offering. Wells Fargo Securities, LLC acted as lead manager and SunTrust Robinson Humphrey, Inc. acted as co-manager for the offering.

No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus dated October 30, 2018 and filed with the SEC on November 1, 2018 pursuant to Rule 424(b) under the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Performance Graph

As a smaller reporting company, we are not required to provide the performance graph required by Item 201(e) of Regulation S-K.

Item 6. Selected Financial Data.

As a smaller reporting company, we are not required to provide the selected financial data required by Item 301 of Regulation S-K.

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

Overview

We are a medical technology company that has developed and is commercializing an innovative and minimally invasive implantable neurostimulation system. SNM therapy is primarily used to treat patients with OAB, including UUI and UUF, FI, and UR.

OAB affects an estimated 87 million adults in the United States and Europe. Another estimated 40 million adults are reported to suffer from FI. SNM therapy is an effective and durable treatment that has been widely used and reimbursed in Europe and the United States for the past two decades. SNM is the only OAB treatment with proven clinical superiority to standard medical therapy and OAB patients who receive SNM report significantly higher quality of life than patients undergoing drug treatment.

We believe our proprietary r-SNM System offers significant advantages, including being the first and only rechargeable SNM system that is designed to be 60% smaller than existing technology and to last approximately 15 years. We believe our r-SNM System has the potential to disrupt and grow the estimated $650 million global SNM market in 2018, which is currently controlled by a single participant.

We currently have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR. On December 3, 2018, we submitted a literature-based PMA application to the FDA for OAB and UR. This literature-based PMA was based on reasonable safety and effectiveness data from a literature review. In this PMA filing, we submitted existing literature reporting on InterStim II. In addition to the technical specifications, testing data and published literature, we included one-year follow-up data from our 51-patient RELAX-OAB European post-market clinical follow-up study to support the PMA, and subsequently provided the FDA with the clinical results on the first 60 patients to reach their six-month primary endpoint from our ARTISAN-SNM pivotal study. Since the original PMA submission in December 2018, we have submitted various amendments to the PMA. These amendments include data in support of conditional full-body magnetic resonance imaging ("MRI") labeling and complete three-month and six-month clinical data from the ARTISAN-SNM study. On March 1, 2019, we submitted a new literature-based PMA seeking approval for FI. This PMA is also based on an existing literature review of Interstim II. Typically, the PMA review process takes six to 18 months, with the duration depending on a variety of factors.

We will continue to maintain our core strategy of pursuing what is, in our view, the most expeditious pathway within the PMA processes to achieving FDA clearance to market the Axonics r-SNM system in the United States. Specifically, it is our understanding that the literature-based PMA submission did not impact the ARTISAN-SNM pivotal study, nor, in our understanding, did the submission of the complete data from our ARTISAN-SNM pivotal study impact the schedule of the literature-based PMA process. The literature-based PMA filing now includes the data from all 129 subjects treated in the ARTISAN-SNM pivotal study and we believe that the question-response process between us and the FDA will prove beneficial in the overall PMA review process. We have retained the option to file a PMA submission at any time based on the ARTISAN-SNM pivotal study data and additional required information, or to rely solely on the literature-based application currently under review, whichever appears to represent, in our judgment, the most efficient and timely pathway to approval.

Since we commenced operations in late 2013, we have generated minimal revenue, as our activities have consisted primarily of developing our r-SNM System, conducting our RELAX-OAB post-market clinical follow-up

study in Europe and our ARTISAN-SNM pivotal study in the United States and Europe, and filing for regulatory approvals.

In the future, if our r-SNM System is approved in the United States, we expect to generate revenue from product sales. Our ability to generate revenue and become profitable will depend on our ability to successfully commercialize our r-SNM System and any product enhancements we may advance in the future. Although we have begun limited commercial activities in Europe, our main priority is the United States, where we expect to begin to commercialize and market our r-SNM System and generate revenue from product sales if and when approved by the FDA. We plan to establish a significant commercial infrastructure in anticipation of potential FDA approval of our r-SNM System and make significant investments to build our sales and marketing organization by hiring dedicated sales personnel, including sales representatives, sales managers and clinical support personnel to market our product in markets throughout United States and Canada. In addition, we plan to strategically expand into certain international markets in Europe. If we are unable to accomplish any of these objectives, it could have a significant negative impact on our future revenue. If we fail to generate revenue in the future, our business, results of operations, financial condition, cash flows, and future prospects would be materially and adversely affected.

We also intend to continue to make investments in research and development efforts to develop our next generation r-SNM System and support our future regulatory submissions for expanded labeling. We expect to derive future revenue by increasing patient and physician awareness of our r-SNM System and obtaining additional regulatory approvals.

In the United States, the cost required to treat each patient is reimbursed through various third-party payors, such as commercial payors and government agencies. 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. 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.

We currently outsource the manufacture of all components of our r-SNM System. We plan to continue with an outsourced manufacturing arrangement for certain of our r-SNM System components for the foreseeable future. We believe that our contract manufacturers are recognized in their field for their competency to manufacture the respective portions of our r-SNM System and have quality systems established that meet FDA requirements. We believe the manufacturers we currently utilize have sufficient capacity to meet our launch requirements and are able to scale up their capacity relatively quickly with limited capital investment.

We have devoted substantially all of our resources to research and development activities related to our r-SNM System, including clinical and regulatory initiatives to obtain marketing approvals. In anticipation of potential FDA approval, we expect to continue to spend a significant amount of our resources on sales and marketing activities as we begin to commercialize and market our r-SNM System in the United States.

We incurred net losses of $32.5 million and $18.1 million for the years ended December 31, 2018 and 2017, and had an accumulated deficit of $99.6 million as of December 31, 2018. As of December 31, 2018, we had available cash, cash equivalents and short-term investments of approximately $157.5 million, current liabilities of approximately $5.9 million, and long-term liabilities of approximately $22.7 million.

Prior to our IPO, we financed our operations primarily through preferred stock financings and amounts borrowed under the Loan Agreement. We have invested heavily in product development and continuous improvement to our r-SNM System. We have also made significant investments in clinical studies to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions. Because of these and other factors, we expect to continue to incur net losses for the next few years and we may require additional funding, which may include future equity and debt financings. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material and adverse effect on our business, financial condition, and results of operations.

Initial Public Offering

On November 2, 2018, we completed our IPO by issuing 9,200,000 shares of common stock, at an offering price of $15.00 per share, inclusive of 1,200,000 shares of our common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The gross proceeds from the IPO were $138.0 million and the net proceeds were approximately $126.0 million, after deducting underwriting discounts, commissions and estimated offering expenses payable by us. In connection with the IPO, our outstanding shares of convertible preferred stock were automatically converted into an aggregate of 15,813,297 shares of common stock, and our outstanding warrants to purchase shares of Series C convertible preferred stock were automatically converted into warrants to purchase up to an aggregate of 80,000 shares of common stock.

AMF License Agreement

On October 1, 2013, we entered into the License Agreement pursuant to which AMF granted us a royalty-bearing, sublicensable license to the AMF IP. The license to the AMF IP allows Axonics to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of:

(i) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body;

(ii) chronic pain in humans through the application of electrical energy to the nervous system; and

(iii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve,

excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system.

We have the right to expand the field of use for the AMF Licensed Products to modulation of digestive process and treatment of digestive conditions in humans through the application of electrical energy anywhere in or on the body, subject to the exclusions described above.

Generally, the license is non-transferable without the prior written consent of AMF, except to an affiliate of our company or in connection with the acquisition of our company (whether by merger, consolidation, sale or otherwise) or the part of our business to which the License Agreement relates, provided that the assignee agrees in writing to be bound to the terms of the License Agreement to which we are bound.

We granted to AMF a royalty-free, worldwide, sublicensable, perpetual, exclusive license to the Axonics Licensed IP. This license granted by us to AMF explicitly excludes uses of the Axonics Licensed IP that are within the scope of the exclusive license of the AMF IP granted by AMF to us. Such license is irrevocable unless we terminate the License Agreement and AMF does not agree to pay us compensation for such license mutually agreed between us and AMF or determined by arbitration in accordance with the terms of the License Agreement. To date, we have not made any improvements to the inventions claimed in the AMF IP that constitute Axonics Licensed IP.

In addition, the License Agreement provides AMF with the AMF Option, to license from us any intellectual property owned by us or otherwise in our control, that is related to electrical stimulation of human tissue, separate from the Axonics Licensed IP and AMF IP, on terms that are materially consistent with the terms upon which we license the AMF IP pursuant to the License Agreement, and subject to field of use restrictions that would be determined upon the exercise of the AMF Option. AMF has expressly declined in writing to exercise the AMF Option.

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF the greater of (i) 4% of all net revenue derived from the AMF Licensed Products, and (ii) the Minimum Royalty, payable quarterly. As of December 31, 2018, we have accrued $0.1 million toward the Minimum Royalty. The Minimum Royalty will automatically increase each year after 2018, subject to a maximum amount of $200,000 per year. We have 60 days to pay AMF the royalty amount due under the License Agreement, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

The initial term of the License Agreement is from October 1, 2013 to October 1, 2033, and will automatically continue until all patents are no longer in force. Upon completion of the initial term, the license granted pursuant to

the License Agreement will be fully paid-up and perpetual except that if we wish to continue to practice any of the patents licensed to us by AMF that remain in force after such initial term, then we will have to continue to pay a reduced royalty for so long as such patent remains in force.

Each party may terminate the License Agreement if the other party commits a material breach of any obligation under the License Agreement and such breach is not cured within 90 days following receipt of notice of such breach from the other party. AMF may terminate the License Agreement upon (i) notice to us in the event we challenge or assist any other person or entity in challenging the patentability, enforceability or validity of any of the AMF patents licensed to us under the License Agreement, subject to certain exceptions including challenges that we are not infringing any such AMF patent, and (ii) upon our filing of or the institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of our assets for the benefit of creditors, and in the case of involuntary bankruptcy, in the event we consent to such bankruptcy and it is not dismissed within 90 days. Lastly, we may terminate the License Agreement in full for any reason effective upon 60 days written notice to AMF.

The License Agreement was amended twice in February 2014 in order to, among other things, include the field of the treatment of urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, within the scope of the licenses granted therein.

The agreement allows for AMF the right to use the AMF IP for non-commercial research, educational and scholarly purposes.

As of December 31, 2018, AMF holds 2,102,970 shares of our common stock. John Petrovich, a former member of our board of directors who retired from the board in early March 2019, is the President, Chief Executive Officer, Senior Vice President, Business Development and General Counsel of AMF.

Components of Our Results of Operations

Net Revenue

Since we commenced operations in late 2013, we have generated minimal revenue, as our activities have consisted primarily of developing our r-SNM System, conducting our RELAX-OAB post-market clinical follow up study in Europe and our ARTISAN-SNM pivotal study in the United States and Europe, and filing for regulatory approvals. In the future, if our r-SNM System is approved in the United States, we expect to generate revenue from product sales. Our ability to generate revenue and become profitable will depend on our ability to successfully commercialize our r-SNM System and any product enhancements we may advance in the future. Although we have begun limited commercial activities in Europe, our main priority is the United States, where we expect to begin to commercialize and market our r-SNM System and generate revenue from product sales if and when approved by the FDA. We plan to establish a significant commercial infrastructure in anticipation of potential FDA approval of our r-SNM System. We expect to derive future revenue by increasing patient and physician awareness of our r-SNM System, hiring our own dedicated sales force, and obtaining additional regulatory approvals. In addition, we plan to strategically expand into favorable international markets. If we are unable to accomplish any of these objectives, it could have a significant negative impact on our future revenue. If we fail to generate revenue in the future, our business, results of operations, financial condition, cash flows, and future prospects would be materially and adversely affected.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of acquisition costs of the components of our r-SNM System, third-party contract labor costs, overhead costs, as well as distribution-related expenses such as logistics and shipping costs, net of costs charged to customers. The overhead costs include the cost of material procurement and operations supervision and management personnel. We expect overhead costs as a percentage of revenue to decrease as our sales volume increases, if our product is approved in the United States. In the future, our cost of goods sold will include expenses associated with our payment of royalties to AMF when we exceed the Minimum Royalty threshold, as well as scrap and inventory obsolescence. The Minimum Royalty amounts are currently included in research and development expenses. We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our revenue grows. We expect gross margin to vary based on regional differences in pricing and discounts negotiated by customers.

We calculate gross margin as gross profit divided by revenue. Revenues have been insignificant to date with prices based on evaluation agreements with one-time discounts offered. We expect future gross margin will be affected by a variety of factors, including manufacturing costs, the average selling price of our r-SNM System, the implementation of cost-reduction strategies, inventory obsolescence costs, which may occur when new generations of our r-SNM System are introduced, and to a lesser extent, the sales mix between the United States, Canada, Europe and Australia as our average selling price in the United States is expected to be higher than in Canada, Europe and Australia. 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 due to seasonality.

Research and Development Expenses

The largest component of our total operating expenses has historically been research and development expenses. Research and development expenses consist primarily of employee compensation, including stock-based compensation, product development, including testing and engineering, and clinical studies to develop and support our r-SNM System, including clinical study management and monitoring, payments to clinical investigators, and data management. Other research and development expenses include consulting and advisory fees, 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 research and development expenses to increase in the future as we develop next generation versions of our r-SNM System and continue to expand our clinical studies to potentially add additional indications and expand to new markets. We expect research and development expenses as a percentage of 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, 2018 and 2017 (in thousands):

	Years Ended December 31,	
	2018	2017
Personnel related	$ 8,452	$ 6,031
Clinical development	4,572	1,562
Contract fabrication and manufacturing	3,572	2,159
Contract R&D and consulting	1,713	1,829
Other R&D expenses	1,093	751
Total R&D expenses	$ 19,402	$ 12,332

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 office-related expenses, facilities and equipment rentals, and travel 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 as a public company including finance personnel and information technology services. Additionally, we anticipate increased expenses related to audit, legal, and tax-related services associated with maintaining compliance with regulations, exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company. These expenses may further increase when we no longer qualify as an “emerging growth company” under the Jumpstart Our Business Startups (JOBS) Act, which will require us to comply with certain reporting requirements from which we are currently exempt. We expect general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of trade shows, booth exhibition costs, and the related travel for these events. Other sales and marketing expenses include consulting and advisory fees, market access personnel and employee compensation, including stock-based compensation. In anticipation of potential FDA approval, we expect sales and marketing expenses to continue to increase in absolute dollars as we expand our commercial infrastructure to both drive and support our expected growth in revenue. In particular, we are in the process of hiring a specialty sales force of approximately 100 sales professionals, regional sales managers and clinical specialists in advance of the anticipated commercial launch of our r-SNM System in the United States, which will significantly increase our sales and marketing expense. However, we expect sales and marketing expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash equivalents and short-term investments, net of interest expense payable under the Loan Agreement with Silicon Valley Bank, and loss on disposal of property and equipment. Other income (expense), net also includes net unrealized mark-to-market gains (losses) on our preferred stock warrant liabilities.

Income Tax Expense

Income tax expense consists of state income taxes in California. We maintain a full valuation allowance for deferred tax assets including net operating loss carryforwards and research and development credits and other tax credits.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following table shows our results of operations for the years ended December 31, 2018 and 2017 (in thousands, except percentages):

	Years Ended December 31,		Period to Period Change
	2018	2017	
Net revenue	$ 707	$ 128	$ 579
Cost of goods sold	356	118	238
Gross profit	351	10	341
Gross Margin	*49.7%*	*7.9%*	
Operating Expenses			
Research and development	19,402	12,332	7,070
General and administrative	9,362	4,823	4,539
Sales and marketing	3,724	1,029	2,695
Total operating expenses	32,488	18,184	14,304
Loss from operations	(32,137)	(18,174)	(13,963)
Other Income (Expense)			
Interest income	998	201	797
Loss on disposal of property and equipment	—	(65)	65
Interest and other expense	(1,343)	(22)	(1,321)
Other income (expense), net	(345)	114	(459)
Loss before income tax expense	(32,482)	(18,060)	(14,422)
Income tax expense	1	1	—
Net loss	$ (32,483)	$ (18,061)	$ (14,422)
Foreign currency translation adjustment	(14)	588	(602)
Comprehensive loss	$ (32,497)	$ (17,473)	$ (15,024)

Net Revenue

Net revenue was $0.7 million in fiscal year 2018 and was derived from the sale of our r-SNM Systems to customers in Europe and Canada. Net revenue was $0.1 million in fiscal year 2017 and consisted of a sale to a single customer in Canada.

Cost of Goods Sold and Gross Margin

We incurred $0.4 million of cost of goods sold in fiscal year 2018, compared to $0.1 million in fiscal year 2017. Gross margin was 49.7% in fiscal year 2018, compared to 7.9% gross margin in fiscal year 2017. The increase in gross margin is primarily due to country and product mix, and the lower gross margin in the prior year period is due to a one-time evaluation agreement with a hospital in Canada.

Research and Development Expenses

Research and development expenses increased $7.1 million, or 57.3%, to $19.4 million in fiscal year 2018, compared to $12.3 million in fiscal year 2017. The increase in research and development expenses was primarily attributable to an increase of $3.0 million in clinical development costs to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions, an increase of $2.4 million in personnel costs including $1.4 million in salaries and wages and $0.6 million in forgiveness of stock subscriptions receivable, and an increase of $1.4 million in contract fabrication and manufacturing costs. For more information on forgiveness of stock subscriptions receivable, see Note 6 to the Consolidated Financial Statements in Part II, Item 8 of this Report.

General and Administrative Expenses

General and administrative expenses increased $4.5 million, or 94.1%, to $9.4 million in fiscal year 2018, compared to $4.8 million in fiscal year 2017, primarily as a result of an increase of $2.6 million related to personnel costs including $1.2 million of forgiveness of stock subscriptions receivable and $0.9 million of salaries and wages, and an increase of $1.1 million in legal and consulting costs. For more information on forgiveness of stock subscriptions receivable, see Note 6 to the Consolidated Financial Statements in Part II, Item 8 of this Report.

Sales and Marketing Expenses

Sales and marketing expenses increased $2.7 million, or 261.6%, to $3.7 million in fiscal year 2018, compared to $1.0 million in fiscal year 2017. The increase in sales and marketing expenses was primarily due to an increase of $1.5 million related to personnel costs and costs of initial hiring of the sales force and an increase of $0.8 million related to expenses for general marketing expenses, conferences and tradeshows.

Other Income (Expense), Net

Other expense, net was $0.3 million in fiscal year 2018, consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank, partially offset by interest income earned on cash equivalents and short-term investments. Other income, net was $0.1 million in fiscal year 2017, which was primarily interest income earned on cash equivalents and short-term investments.

Income Tax Expense

Income tax expense was minimal in fiscal year 2018 and 2017.

Liquidity and Capital Resources

Since we commenced operations in late 2013, we have devoted substantially all of our resources to research and development activities related to our r-SNM System, including clinical and regulatory initiatives to obtain marketing approvals. Additionally, to date, we have generated minimal revenue from product sales and have never been profitable. While we have received regulatory approval in Europe, Canada, and Australia for OAB, FI, and UR, our main commercial priority is the United States, where we expect to begin to commercialize and market our r-SNM System initially for the treatment of OAB and UR, and generate revenue from product sales if and when approved by the FDA. In addition to the United States, we expect to expend capital resources pursuing commercial operations in Europe, Canada, and Australia, the amount and timing of which will depend on a variety of factors, including the size of the developed market for SNM therapy, burdens to entry in any such country or region, and other factors specific to certain respective countries and regions.

We incurred net losses of $32.5 million and $18.1 million for the years ended December 31, 2018 and 2017, respectively, and had an accumulated deficit of $99.6 million as of December 31, 2018. In anticipation of potential FDA approval, we expect to spend a significant amount of our existing resources on sales and marketing activities as we begin to commercialize and market our r-SNM System in the United States. In particular, we are in the process of hiring a specialty sales force of approximately 100 sales professionals, regional sales managers and clinical specialists in advance of the anticipated commercial launch of our r-SNM System in the United States, which will significantly increase our sales and marketing expense.

As of December 31, 2018, we had cash, cash equivalents and short-term investments of $157.5 million. Since inception and prior to our IPO, we raised an aggregate of $114.2 million in gross proceeds from private placements of our preferred stock. On October 30, 2018, we completed our IPO by issuing 9,200,000 shares of common stock, at an

offering price of $15.00 per share, for net proceeds of approximately $126.0 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Prior to the IPO, our primary sources of capital were from equity financings and amounts borrowed under the Loan Agreement with Silicon Valley Bank. In February 2018, we received $10.0 million from the first tranche ("Tranche A") of the Term Loan simultaneously with our entry in the Loan Agreement. In October 2018, we received the full $5.0 million from the second tranche ("Tranche B") and the full $5.0 million from ("Tranche C"). As of December 31, 2018, we had $21.5 million in outstanding borrowings, as discussed below under "Indebtedness." We believe that our existing cash resources will be sufficient to meet our forecasted requirements for operating liquidity, capital expenditure and debt repayments for at least the next 12 months from the issuance of this Annual Report. If these sources are insufficient to satisfy our liquidity requirements, however, we may seek to sell additional equity, increase the availability under the Loan Agreement or enter into an additional loan agreement. 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 delay the development, commercialization and marketing of our r-SNM System.

Cash Flows

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

	Years Ended December 31,	
	2018	**2017**
Net cash provided by (used in)		
Operating activities	$ (31,370)	$ (18,175)
Investing activities	(60,050)	(1,039)
Financing activities	165,342	34,815
Effect of exchange rate changes on cash and cash equivalents	(14)	588
Net increase (decrease) in cash and cash equivalents	$ 73,908	$ 16,189

Net cash used in operating activities

Net cash used in operating activities was $31.4 million in fiscal year 2018 and consisted primarily of a net loss of $32.5 million, a decrease in net operating assets of $2.9 million, partially offset by non-cash charges of $4.0 million. Net operating assets consisted primarily of inventory to support the planned launch of our commercial operations. Non-cash charges consisted primarily of forgiveness of receivables for stock subscriptions, depreciation and amortization, and stock-based compensation.

Net cash used in operating activities was $18.2 million in fiscal year 2017 and consisted primarily of a net loss of $18.1 million, a decrease in net operating assets of $1.4 million, partially offset by non-cash charges of $1.3 million. Net operating assets consisted primarily of inventory to support the planned launch of our commercial operations. Non-cash charges consisted primarily of depreciation and amortization and stock-based compensation.

Net cash used in investing activities

Net cash used in investing activities was $60.1 million in fiscal year 2018 and consisted primarily of purchases and sales of short-term investments.

Net cash used in investing activities was $1.0 million in fiscal year 2017 and consisted of purchases of property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities was $165.3 million in fiscal year 2018 and consisted primarily of $126.0 million in net proceeds received in the IPO, $20.0 million of proceeds from our Term Loan with Silicon Valley Bank, and $20.1 million of proceeds from the issuance of shares of our Series C preferred stock.

Net cash provided by financing activities was $34.8 million in fiscal year 2017 and consisted primarily of $35.0 million of proceeds from the issuance and sale of our Series C preferred stock.

Indebtedness

In February 2018, we entered into a Loan and Security Agreement with Silicon Valley Bank, which we and Silicon Valley Bank amended in October 2018, providing for the Term Loan. Pursuant to the Loan Agreement, we have drawn $20.0 million in three tranches of term loans, with such drawn obligations maturing on December 1, 2021.

The Loan Agreement provides for monthly interest payments through December 31, 2019. On the first day of the end of the interest only period, we will be required to repay the Term Loan in equal monthly installments of principal plus interest through maturity. Outstanding principal balances under the Term Loan bear interest at the prime rate plus 1.75%.

We may prepay amounts outstanding under the Term Loan in increments of $5.0 million at any time with 30 days prior written notice to Silicon Valley Bank. However, all prepayments of the Term Loan prior to maturity, whether voluntary or mandatory (acceleration or otherwise), are also subject to the payment of a prepayment fee equal to (i) for a prepayment made on or after the closing date through and including the first anniversary of the closing date, 3.00% of the principal amount of the Term Loan being prepaid, (ii) for a prepayment made after the date which is the first anniversary of the closing date through and including the second anniversary of the closing date, 2.00% of the principal amount of the Term Loan being prepaid, and (iii) for a prepayment made after the date which is the second anniversary of the closing date and before the maturity date, 1.00% of the principal amount of the Term Loan being prepaid. Additionally, on the earliest to occur of (i) the maturity date of the Term Loan, (ii) the acceleration of the Term Loan, or (iii) the prepayment of the Term Loan, we will be required to make a final payment equal to the original principal amount of such Tranche multiplied by 7.50%. We are currently accruing the portion of the final payment calculated based on the amount outstanding under the Term Loan.

All obligations under the Term Loan are secured by a first priority lien on substantially all of our assets, excluding intellectual property assets and more than 65% of the shares of voting capital stock of any of our foreign subsidiaries. We have agreed with Silicon Valley Bank not to encumber our intellectual property assets without its prior written consent unless a security interest in the underlying intellectual property is necessary to have a security interest in the accounts and proceeds that are part of the assets securing the Term Loan, in which case our intellectual property shall automatically be included within the assets securing the Term Loan.

The Loan Agreement contains certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interest. Subject to certain limited exceptions, these covenants limit our ability to or prohibit us to permit any of our subsidiaries to, as applicable, among other things:

- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of our capital stock;
- convey, sell, lease, transfer, assign, or otherwise dispose of all or any part of our business or property;
- effect certain changes in our business, management, ownership or business locations;
- merge or consolidate with, or acquire all or substantially all of the capital stock or property of any other company;
- create, incur, assume, or be liable for any additional indebtedness, or create, incur, allow, or permit to exist any additional liens;
- make certain investments; and
- enter into transactions with our affiliates.

While we have not previously breached and are currently in compliance with the covenants contained in the Loan Agreement, we may breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, Silicon Valley Bank may choose to declare an event of default and require that we immediately repay all amounts outstanding under the Loan Agreement, terminate any commitment to extend further credit and foreclose on the collateral. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations. An event of default includes, but is not limited to, the following: if we fail to make any payment under the Loan Agreement when due, if we fail or neglect to perform certain obligations under the Loan Agreement, if we violate certain covenants under the Loan Agreement, if certain material adverse changes occur, if we are unable to pay our debts as they become due or otherwise become insolvent, or if we begin an insolvency proceeding.

In addition, we issued warrants to Silicon Valley Bank and Life Science Loans II, LLC, its counterparty. Each warrant entitles the holder thereof to purchase 40,000 shares of our common stock at an exercise price of $7.50 per share. Each warrant will expire on February 6, 2028.

We have no further indebtedness arrangements.

Off-Balance Sheet Arrangements

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.

Critical Accounting Policies and 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 amounts reported in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable and supportable 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 under different assumptions or conditions, and such differences may be material to our consolidated financial statements.

While our significant accounting policies are more fully described in Note 1 to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue Recognition

Since we commenced operations in late 2013, we have recognized minimal revenue. Although we have begun limited commercial activities in the EU, our main priority is the United States where we expect to begin to commercialize and market our r-SNM System and generate revenue from product sales if and when approved by the FDA. In addition, we plan to strategically expand into favorable international markets. If we are unable to accomplish any of these objectives, it could have a significant negative impact on our future revenue. If we fail to generate revenue in the future, our business, results of operations, financial condition, cash flows and future prospects would be materially and adversely affected.

Revenue recognized during the years ended December 31, 2018 and 2017 relates entirely to the sale of our r-SNM System. In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09 “Revenue from Contracts with Customers” (“ASU 2014-09”) as Accounting Standards Codification (“ASC”) Topic 606. The objective of Topic 606 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and superseded most of the existing revenue recognition guidance, including industry-specific guidance. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Topic 606 applies to all contracts with customers except those that are within the scope of other topics in the FASB ASC. Effective January 1, 2018, we early adopted the comprehensive new revenue recognition standard using the modified retrospective method.

We make reasonable assumptions regarding the future collectability of amounts receivable from customers to determine whether the revenue recognition criteria have been met. Taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer are not recorded as revenue. In general, our standard terms and conditions of sale do not allow for product returns. We expense shipping and handling costs as incurred and include them in the cost of goods sold.

In those cases where shipping and handling costs are billed to customers, we classify the amounts billed as a component of cost of goods sold.

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 our assumptions and valuation techniques used to measure assets and liabilities at fair value. The inputs require significant management judgment or estimation.

Our 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, accounts payables, and accrued expenses, due to their short-term nature. The carrying amount of our term loan, which is described below, approximates fair value, considering the interest rates are based on the prime interest rate.

Investment Securities

We classify our investment securities as available-for-sale. Those investments in debt securities with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments in debt securities with maturities greater than 12 months at the date of purchase are considered long-term investments. Our 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 interest income within the consolidated statement of comprehensive income (loss).

Inventory

Inventories are stated at the lower of cost or net realizable value, with cost computed on a first-in, first-out basis.

We capitalize inventory produced for commercial sale. Costs associated with developmental products prior to satisfying our inventory capitalization criteria are charged to research and development expense as incurred.

Products that have been approved by certain regulatory authorities are also 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 clinical programs is identical and, as a result, the inventory has an “alternative future use” as defined in authoritative guidance. Component materials and purchased products associated with clinical development programs are included in inventory and charged to research and development expense 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 expense when the inventory ownership transfers to us.

We analyze 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 r-SNM System 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 our inventory values. We also apply 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 we continually gather information regarding product quality for periods after the manufacturing date. The r-SNM System currently has a maximum estimated shelf life range of 12 to 27 months and, based on sales forecasts, we expect 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 or not inventory costs will be realizable requires estimates by our 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.

We began capitalizing the r-SNM System manufacturing costs as inventory following both the receipt of regulatory approval from the European and Canadian regulatory bodies and the Company's intent to commercialize, which occurred in 2017. As of December 31, 2018, we had $0.9 million and $2.7 million of finished goods inventory and raw materials inventory, respectively, on hand. As of December 31, 2017, we had $0.2 million and $1.3 million of finished goods inventory and raw materials inventory, respectively, on hand. As of December 31, 2018 and 2017, there were minimal work-in-process inventory on hand.

Intangible 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. 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 is 8.71 years. We will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date.

Impairment of Long-Lived Assets

We review our 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 have been no such impairments of long-lived assets to date.

Leases

We determine if an arrangement is a lease at inception and include operating leases on our consolidated balance sheets. The operating lease right-of-use ("ROU") asset is included within our other non-current assets, and lease liabilities are included in current or noncurrent liabilities on our consolidated balance sheets.

Operating lease ROU asset 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 our lease does not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The lease terms may include options to extend or terminate the lease when it is reasonably certain that we 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 salary and personnel-related costs, costs of clinical studies and testing, supplies and materials, and outside consultant costs. Costs of clinical studies and testing include fees paid to hospitals and physicians for the enrollment and treatment of patients, related product manufacturing expenses for the products used in the studies, fees paid to CROs, other consultants, and other outside expenses.

Our research and development team focuses on our r-SNM System, including our clinical studies, as well as evaluations of improvements and enhancements to our r-SNM System. For the years ended December 31, 2018 and 2017, we incurred research and development expenses of $19.4 million and $12.3 million, respectively.

Income Taxes

We account 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. We have deferred tax assets. The realization of these deferred tax assets is dependent upon our 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. We evaluate the recoverability of the deferred tax assets annually. We recognize 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. We have determined that we have no uncertain tax positions.

Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentives for employees and certain advisors and consultants. The plan allows for the issuance of nonstatutory and incentive stock options to employees and nonstatutory stock options to consultants and non-employee directors.

We measure the cost of employee services in exchange for an award of equity instruments based on the grant-date fair value of the award and recognize compensation cost over the requisite service period (typically the vesting period), generally four years. We account for equity instruments issued to non-employees based on the fair value of the award, which is periodically re-measured as they vest over the performance period. The related expense is recognized over the performance period.

We estimate the fair value of stock options using the Black-Scholes option pricing model. We use the value of our common stock to determine the fair value of restricted shares.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate, and (iv) the expected dividend yield. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based the estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. Similarities with such companies include being at the stage of product development and focused on the medical technology industry. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. We use the simplified method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

Internal Controls and Procedures

We will be required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the year following our first annual report required to be filed with the SEC. This assessment will need to include disclosure of any material weaknesses identified by management over our internal control over financial reporting. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial

reporting pursuant to Section 404(b) until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" if we take advantage of the exemptions contained in the JOBS Act.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are designed and operating effectively, which could result in a loss of investor confidence in the accuracy and completeness of our financial reports. This could cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC.

Recent Accounting Pronouncements

For recent accounting pronouncements, see Note 1, Nature of Operations and Summary of Significant Accounting Policies, of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

JOBS Act

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company," as defined in the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include:

- an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- reduced disclosure about executive compensation arrangements in our periodic reports, registration statements and proxy statements;
- exemptions from the requirements to seek non-binding advisory votes on executive compensation or golden parachute arrangements; and
- delay implementing new accounting standards until such time as those standards apply to private companies.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue is $1.07 billion or more or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this Annual Report on Form 10-K and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

We have elected not to delay implementing new accounting standards until such time as those standards apply to private companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

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

As a smaller reporting company, we are not required to provide the information required by Item 305 of Regulation S-K.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Axonics Modulation Technologies, Inc. (the "Company") and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of comprehensive loss, mezzanine equity, stockholders' equity (deficit), and cash flows for the years then ended, 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 and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) ("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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ BDO USA, LLP

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

Costa Mesa, California
March 5, 2019

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

	December 31,	
	2018	**2017**
ASSETS		
Current assets		
Cash and cash equivalents	$ 98,306	$ 24,398
Short-term investments	59,218	—
Accounts receivable	427	—
Inventory	3,673	1,541
Prepaid expenses and other current assets	3,716	980
Total current assets	165,340	26,919
Property and equipment, net	2,784	1,530
Intangible asset, net	426	541
Other assets	3,356	422
Total assets	$ 171,906	$ 29,412
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 3,436	$ 1,616
Accrued liabilities	1,683	789
Lease liability, current portion	768	—
Total current liabilities	5,887	2,405
Lease liability, net of current portion	3,281	135
Debt, net of unamortized debt issuance costs	19,463	—
Total liabilities	28,631	2,540
Mezzanine Equity		
Convertible Preferred Stock		
Series A Convertible Preferred Stock, par value $0.0001, no shares authorized, issued, and outstanding at December 31, 2018; 1,030,000 shares authorized, 719,500 shares issued and outstanding at December 31, 2017; aggregate liquidation preference of $0 and $15,829 at December 31, 2018 and 2017, respectively	—	14,021
Series B-1 Convertible Preferred Stock, par value $0.0001, no shares authorized, issued, and outstanding at December 31, 2018; 2,529,862 shares authorized, 1,925,302 shares issued and outstanding at December 31, 2017; aggregate liquidation preference of $0 and $15,248 at December 31, 2018 and 2017, respectively	—	13,757
Series B-2 Convertible Preferred Stock, par value $0.0001, no shares authorized, issued, and outstanding at December 31, 2018; 2,537,231 shares authorized, 2,213,794 shares issued and outstanding at December 31, 2017; aggregate liquidation preference of $0 and $19,481 at December 31, 2018 and 2017, respectively	—	17,572
Series C Convertible Preferred Stock, par value $0.0001, no shares authorized, issued, and outstanding at December 31, 2018; 3,888,889 shares authorized, 1,898,213 shares issued and outstanding at December 31, 2017; aggregate liquidation preference of $0 and $17,084 at December 31, 2018 and 2017, respectively	—	16,877
Noncontrolling interest in Axonics Europe, S.A.S.	—	31,066
Stockholders' Equity (Deficit)		
Preferred Stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2018; no shares authorized, issued, and outstanding at December 31, 2017	—	—
Common Stock, par value $0.0001, 50,000,000 and 15,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 27,806,934 and 2,776,583 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	3	—
Additional paid-in capital	243,337	2,900
Stock subscriptions receivable	—	(1,753)
Accumulated deficit	(99,649)	(67,166)
Accumulated other comprehensive loss	(416)	(402)
Total stockholders' equity (deficit)	143,275	(66,421)
Total liabilities, mezzanine equity and stockholders' equity (deficit)	$ 171,906	$ 29,412

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2018	**2017**
Net revenue	$ 707	$ 128
Cost of goods sold	356	118
Gross profit	351	10
Operating Expenses		
Research and development	19,402	12,332
General and administrative	9,362	4,823
Sales and marketing	3,724	1,029
Total operating expenses	32,488	18,184
Loss from operations	(32,137)	(18,174)
Other Income (Expense)		
Interest income	998	201
Loss on disposal of property and equipment	—	(65)
Interest and other expense	(1,343)	(22)
Other income (expense), net	(345)	114
Loss before income tax expense	(32,482)	(18,060)
Income tax expense	1	1
Net loss	(32,483)	(18,061)
Foreign currency translation adjustment	(14)	588
Comprehensive loss	$ (32,497)	$ (17,473)
Net loss per share, basic and diluted (see Note 1)	$ (4.64)	$ (7.04)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	6,997,777	2,564,964

See accompanying notes to consolidated financial statements.

Axonics Modulation Technologies, Inc.
Consolidated Statements of Mezzanine Equity
(in thousands, except share and per share data)

	Series A Preferred Stock		Series B-1 Preferred Stock		Series B-2 Preferred Stock		Series C Preferred Stock		Noncontrolling	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Interests	Total
Balance at December 31, 2016	719,500	$ 14,021	1,925,302	$ 13,757	2,213,794	$ 17,572	—	$ —	$ 13,150	$ 58,500
Issuance of Series C Preferred Stock at $9.00 per share for cash, net of issuance costs of $207	—	—	—	—	—	—	1,898,213	16,877	17,916	34,793
Balance at December 31, 2017	719,500	14,021	1,925,302	13,757	2,213,794	17,572	1,898,213	16,877	31,066	93,293
Issuance of Series C Preferred Stock at $9.00 per share for cash, net of issuance costs of $199	—	—	—	—	—	—	2,233,333	19,899	—	19,899
Conversion of preferred stock to common stock	(719,500)	(14,021)	(1,925,302)	(13,757)	(2,213,794)	(17,572)	(4,131,546)	(36,776)	(31,066)	(113,192)
Balance at December 31, 2018	—	$ —	—	$ —	—	$ —	—	$ —	$ —	$ —

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in	Stock Subscriptions	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Receivable	Deficit	Loss	Total
Balance at December 31, 2016	2,329,612	$ —	$ 1,843	$ (1,179)	$ (49,105)	$ (990)	$ (49,431)
Issuance of common stock for employee stock option exercises for promissory notes	424,788	—	574	(574)	—	—	—
Issuance of common stock for employee stock option exercises for cash	22,183	—	22	—	—	—	22
Stock-based compensation	—	—	461	—	—	—	461
Foreign currency translation adjustment	—	—	—	—	—	588	588
Net loss	—	—	—	—	(18,061)	—	(18,061)
Balance at December 31, 2017	2,776,583	—	2,900	(1,753)	(67,166)	(402)	(66,421)
Issuance of common stock for employee stock option exercises for promissory notes	48,720	—	71	(71)	—	—	—
Issuance of common stock for employee stock option exercises for cash	7,120	—	9	—	—	—	9
Warrants for common stock	—	—	986	—	—	—	986
Repurchase of common stock	(38,786)	—	(473)	—	—	—	(473)
Forgiveness of stock subscriptions receivable	—	—	—	1,824	—	—	1,824
Conversion of preferred stock to common stock	15,813,297	2	113,190	—	—	—	113,192
Initial public offering - issuance of 9,200,000 shares at $15.00 per share, less closing costs of $11,951	9,200,000	1	126,048	—	—	—	126,049
Stock-based compensation	—	—	606	—	—	—	606
Foreign currency translation adjustment	—	—	—	—	—	(14)	(14)
Net loss	—	—	—	—	(32,483)	—	(32,483)
Balance at December 31, 2018	27,806,934	$ 3	$ 243,337	$ —	$ (99,649)	$ (416)	$ 143,275

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2018	**2017**
Cash Flows from Operating Activities		
Net loss	$ (32,483)	$ (18,061)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	946	725
Loss on disposal of property and equipment	—	65
Stock-based compensation	606	461
Forgiveness of stock subscriptions receivable	1,824	—
Amortization of debt issuance costs	338	—
Change in fair value of warrants	254	—
Changes in operating assets and liabilities		
Accounts receivable	(427)	—
Inventory	(2,255)	(1,541)
Prepaid expenses and other current assets	(3,009)	(459)
Other assets	65	(199)
Accounts payable	1,820	985
Accrued liabilities	1,060	(53)
Lease liability	(109)	(98)
Net cash used in operating activities	(31,370)	(18,175)
Cash Flows from Investing Activities		
Purchases of property and equipment	(1,228)	(1,039)
Purchases of short-term investments	(78,122)	—
Proceeds from sale of short-term investments	19,300	—
Net cash used in investing activities	(60,050)	(1,039)
Cash Flows from Financing Activities		
Payment of debt issuance costs	(142)	—
Proceeds from debt	20,000	—
Proceeds from exercise of stock options	9	22
Proceeds from issuance of common stock upon initial public offering	138,000	—
Payment of common stock issuance costs upon initial public offering	(11,951)	—
Proceeds from issuance of preferred stock and noncontrolling interest	20,098	35,000
Payment of preferred stock issuance costs	(199)	(207)
Repurchase of common stock	(473)	—
Net cash provided by financing activities	165,342	34,815
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(14)	588
Net increase (decrease) in cash and cash equivalents	73,908	16,189
Cash and cash equivalents, beginning of year	24,398	8,209
Cash and cash equivalents, end of year	$ 98,306	$ 24,398
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ 751	$ —
Cash paid for taxes	$ 1	$ 1
Noncash Investing and Financing Activities		
Common stock issuance on stock option exercises for promissory notes	$ 71	$ 574
Warrants issued as debt issuance costs	$ 733	$ —
Accrued loan fees as debt issuance costs	$ 1,500	$ —
Forgiveness of stock subscriptions receivable	$ 1,824	$ —

See accompanying notes to consolidated financial statements.

AXONICS MODULATION TECHNOLOGIES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Nature of Operations

Axonics Modulation Technologies, Inc. (the "Company"), formerly American Restorative Medicine, Inc., was incorporated in the state of Delaware on March 2, 2012. 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. The Company is a medical technology company focused on the design, development, and commercialization of innovative and minimally invasive sacral neuromodulation solutions. The Company has designed and developed the r-SNM System, which delivers 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 r-SNM System is protected by intellectual property based on Company-generated innovations and patents and other intellectual property licensed from AMF. To date, the Company has obtained marketing approvals in Europe, Canada, and Australia for OAB, UR, and FI. The Company has derived minimal revenue from its operations, and its activities have consisted primarily of developing the r-SNM System, conducting its RELAX-OAB post-market clinical follow-up study in Europe, and its ARTISAN-SNM pivotal clinical study in the United States.

Initial Public Offering

On November 2, 2018, the Company completed its initial public offering ("IPO") by issuing 9,200,000 shares of common stock, at an offering price of $15.00 per share, inclusive of 1,200,000 shares of the Company's common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The net proceeds were approximately $126.0 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company. In connection with the IPO, the Company's outstanding shares of convertible preferred stock were automatically converted into an aggregate of 15,813,297 shares of common stock, and the Company's outstanding warrants to purchase shares of Series C convertible preferred stock were automatically converted into warrants to purchase up to an aggregate of 80,000 shares of common stock (see Note 6).

Principles of Consolidation

The consolidated financial statements include the accounts of the Company, its wholly-owned subsidiaries, Axonics Modulation Technologies U.K. Limited and Axonics Modulation Technologies Australia Pty Ltd. Prior to the IPO, Axonics Europe, S.A.S. was considered a variable interest entity, in which the Company exercises control and is determined to be the primary beneficiary. The interests held by the other investors in Axonics Europe can be converted at any time into a fixed number of shares of the Company's preferred stock pursuant to the terms of a Fourth Amended and Restated Share Exchange Agreement, dated June 30, 2017 (the "Share Exchange Agreement"). Due to this conversion right, the investors' interests are considered to be protected from any losses in Axonics Europe (see Note 6). Therefore, the Company is considered responsible for absorbing the losses of Axonics Europe and as such, has a variable interest in Axonics Europe. Axonics Europe has no equity at risk and is therefore considered a variable interest entity since it is dependent on the Company to finance its activities. The investors in Axonics Europe have entered into an agreement with the Company acknowledging that their investment is not intended to give them voting control over Axonics Europe and they have agreed to vote as directed by the Company's board of directors. Therefore, the Company is the primary beneficiary of Axonics Europe and consolidates this entity. Upon the Company's IPO on November 2, 2018, the convertible shares in Axonics Europe were converted into shares of Axonics Modulation Technologies, Inc. and therefore at December 31, 2018 the European entity is deemed a wholly-owned subsidiary. Axonics Modulation Technologies U.K. Limited and Axonics Europe, S.A.S. did not have significant operations for the years ended December 31, 2018 and 2017. 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").

Stock Split and Charter Amendment

In October 2018, the board of directors and certain stockholders of the Company approved an amendment to the Company's Certificate of Incorporation to (i) increase the authorized shares of common stock from 17,500,000 to 20,500,000, (ii) effect a 1.2-for-1 forward stock split of the Company's common stock and (iii) define a "Qualified IPO" to include a per share price equal to at least $12.00 (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like). All shares of common stock, stock options, and per share information presented in the consolidated financial statements have been adjusted to reflect the stock split on a retroactive basis for all periods presented. Any fractional shares that resulted from the stock split were rounded up to the nearest whole share. There was no change in the par value of the Company's common stock. The ratios by which shares of preferred stock are convertible into shares of common stock have been adjusted to reflect the effects of the forward stock split.

In November 2018, the board of directors and certain stockholders of the Company approved an amendment to the Company's Certificate of Incorporation to increase the authorized shares of common stock from 20,500,000 to 50,000,000 and authorize 10,000,000 of preferred stock.

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 disclosure 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 under different assumptions or conditions, and such differences may be material to the consolidated financial statements.

Revenue Recognition

Revenue recognized during the years ended December 31, 2018 and 2017 relates entirely to the sale of our r-SNM System. In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09 "Revenue from Contracts with Customers" ("ASU 2014-09") as Accounting Standards Codification ("ASC") Topic 606. The objective of Topic 606 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and superseded most of the existing revenue recognition guidance, including industry-specific guidance. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Topic 606 applies to all contracts with customers except those that are within the scope of other topics in the FASB ASC. Effective January 1, 2018, the Company early adopted the comprehensive new revenue recognition standard using the modified retrospective method. As the Company generated minimal revenue through the date of adoption, the adoption of this guidance did not have a material impact on the Company's consolidated financial statements or related disclosures.

Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments purchased with an original 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.

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.

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, accounts payables, and accrued expenses, due to their short-term nature. The carrying amount of the Company's term loan, which is described below, approximates fair value, considering the interest rates are based on the prime interest rate.

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 date of purchase are considered short-term investments. Those investments in debt securities with maturities greater than 12 months at the date of purchase 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 interest income within the consolidated statement of comprehensive income (loss). There were no unrealized gains or losses during the years ended December 31, 2018 and 2017.

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 new cost basis 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 and interest income are recognized when earned. Realized gains or losses are included in net income (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, 2018 (in thousands):

	Fair Value Measurements			
Assets:	**Level 1**	**Level 2**	**Level 3**	**Total**
Commercial paper	$ —	$ 32,163	$ —	$ 32,163
Corporate notes	12,606	3,156	—	15,762
U.S. government and agency securities	11,293	—	—	11,293
	$ 23,899	$ 35,319	$ —	$ 59,218

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. Costs 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 (deficit) in accumulated other comprehensive 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, 2018 and 2017, all foreign currency translation gains (losses) have been unrealized and included in accumulated other comprehensive loss. Accumulated other comprehensive loss consists entirely of losses from translation of foreign subsidiaries at December 31, 2018 and 2017. Foreign currency transaction gains and losses are included in results of operations and have not been significant for the periods presented.

Inventory

Inventories are stated at the lower of cost or net realizable value, with cost computed on a first-in, first-out basis.

The Company capitalizes inventory produced for commercial sale. Costs associated with developmental products prior to satisfying the Company's inventory capitalization criteria are charged to research and development expense as incurred.

Products that have been approved by certain regulatory authorities are also 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 clinical programs is identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance. Component materials and purchased products associated with clinical development programs are included in inventory and charged to research and development expense 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 expense 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 r-SNM System 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 r-SNM System currently has a maximum estimated shelf life range of 12 to 27 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 or not inventory costs will be realizable 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.

The Company began capitalizing the r-SNM System manufacturing costs as inventory following both the receipt of regulatory approval from the European and Canadian regulatory bodies and the Company's intent to commercialize, which occurred in 2017. As of December 31, 2018, the Company had $0.9 million and $2.7 million of finished goods inventory and raw materials inventory, respectively, on hand. As of December 31, 2017, the Company had $0.2 million and $1.3 million of finished goods inventory and raw materials inventory, respectively, on hand. As of December 31, 2018 and 2017, there were minimal work-in-process inventory on hand.

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.

Intangible 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. 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 is 8.71 years. The Company will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date.

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 have been no such impairments of long-lived assets to date.

Leases

Through December 31, 2017, the Company recognized rent expense related to operating leases on a straight-line basis over the terms of the leases and, accordingly, recorded the difference between cash rent payments and recognition of rent expense as a deferred rent liability. Landlord-funded leasehold improvements were also recorded as deferred rent liabilities and were amortized as a reduction of rent expense over the noncancelable term of the related operating lease.

Effective January 1, 2018, the Company early adopted ASU No. 2016-02, “Leases (Topic 842)”, the comprehensive new lease standard issued by the FASB. The most significant impact was the recognition of right-of-use (“ROU”) assets and lease liabilities for operating leases. Adoption of the standard required us to restate certain previously reported results, including the recognition of additional ROU assets and lease liabilities for existing operating leases. The Company recorded an ROU asset of approximately $0.1 million on its consolidated balance sheet at December 31, 2017 related to its existing operating lease. The Company also recorded a lease liability of $0.3 million on its consolidated balance sheet at December 31, 2017 related to its existing operating lease. The initial adoption of this standard did not have an impact on the Company’s consolidated statements of comprehensive loss. The Company determines if an arrangement is a lease at inception and includes operating leases on the Company’s consolidated balance sheets. The operating lease ROU asset is included within the Company’s other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company’s consolidated balance sheets.

Operating lease ROU asset 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 lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. 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. As of December 31, 2018 and 2017, the remaining lease terms for all of the Company’s operating leases were 6.6 years and 1.8 years, respectively. The discount rate used to determine the present value of all of the Company’s operating leases’ future payments was 6.75% (see Note 4 regarding the new lease).

Noncontrolling Interests

Noncontrolling interests reflected in mezzanine equity are adjusted to the greater of their fair value or carrying value as of each balance sheet date through a charge to additional paid-in capital, if necessary. If classification and presentation outside of permanent equity is not considered necessary, noncontrolling interests are presented as a component of permanent equity on our consolidated balance sheets. On the Company’s consolidated statements of comprehensive loss, expenses and net loss from less-than-wholly-owned consolidated subsidiaries are reported at the consolidated amounts, including both the amounts attributable to the Company and noncontrolling interests.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include salary and personnel-related costs, costs of clinical studies and testing, supplies and materials, and outside consultant costs.

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 deferred tax assets. 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. 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 has determined that it has no uncertain tax positions.

Stock-Based Compensation

The Company measures the cost of 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 four years. The Company accounts for equity instruments issued to non-employees based on the fair value of the award, which is periodically re-measured as they vest over the performance period. The related expense is recognized over the performance period.

Preferred Stock

As provided for in the Company's Certification of Incorporation, liquidation relates to each of the following:

- acquisition of the Company by another entity through a reorganization, merger or consolidation by with the Company's existing stockholders do not continue to hold more than 50% of the surviving or acquiring entity;
- transactions (or series of transactions) in which stockholders transfer more than 50% of the voting power of the Company;
- sale or disposition of substantially all of the Company's assets; and
- any liquidation, dissolution or winding up of the Company.

Certain of the above items are considered deemed redemption features that are not solely in the control of the Company. As a result, prior to the IPO, the Company's convertible preferred stock is classified as mezzanine equity on the consolidated balance sheets. However, as each of the deemed liquidation events are not considered probable of occurring, the instruments are not required to be re-measured in the reporting period. In connection with the Company's IPO, all the existing preferred stock was converted to common stock.

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, convertible preferred stock, preferred stock warrants, and common stock options 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, 2018 and 2017, there were 9,192,127 and 8,059,999 potentially dilutive 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.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, a comprehensive new revenue recognition standard that will supersede previous existing revenue recognition guidance. The standard is intended to clarify the principles of recognizing revenue and create common revenue recognition guidance between GAAP and International Financial Reporting Standards. The standard also requires expanded disclosures surrounding revenue recognition. During fiscal

year 2016, the FASB issued additional clarification guidance on the new revenue recognition standard which also included certain scope improvements and practical expedients. The Company early adopted this guidance effective January 1, 2018 using the modified retrospective method. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements or related disclosures.

In January 2016, the FASB issued ASU No. 2016-01 Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities. The guidance requires entities to measure equity investments that are not accounted for under the equity method at fair value, with any changes in fair value included in current earnings, and updates certain disclosure requirements. The update is effective for fiscal years beginning after December 15, 2017, which was the Company's first quarter of fiscal year 2018. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements or related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)", a comprehensive new lease standard that will supersede previous lease guidance. The standard requires a lessee to recognize assets and liabilities related to long-term leases that were classified as operating leases under previous guidance in its balance sheet. An asset would be recognized related to the right to use the underlying asset and a liability would be recognized related to the obligation to make lease payments over the term of the lease. The standard also requires expanded disclosures surrounding leases. The Company early adopted this guidance effective January 1, 2018 using the modified retrospective method. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases. Adoption of the standard required the Company to restate certain previously reported results, including the recognition of additional ROU assets and lease liabilities for operating leases.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting", which simplifies authoritative guidance to simplify the accounting for certain aspects of share-based compensation. This guidance addresses the accounting for income tax effects at award settlement, the use of an expected forfeiture rate to estimate award cancellations prior to the vesting date and the presentation of excess tax benefits and shares surrendered for tax withholdings on the statement of cash flows. The Company adopted this guidance effective January 1, 2018. This guidance requires all income tax effects of awards (resulting from an increase or decrease in the fair value of an award from grant date to the vesting date) to be recognized in the income statement when the awards vest or are settled which is a change from previous guidance that required such activity to be recorded in paid-in capital within stockholders' equity. Under this guidance, excess tax benefits are also excluded from the assumed proceeds available to repurchase shares in the computation of diluted earnings (loss) per share. This guidance also eliminates the requirement to estimate forfeitures, but rather provides for an election that would allow entities to account for forfeitures as they occur. The Company made an entity-wide accounting policy election to continue to estimate the number of awards that are expected to vest. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements or related disclosures.

In October 2016, the FASB issued ASU No. 2016-16, "Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory", which amends the accounting for income taxes on intra-entity transfers of assets other than inventory. This guidance requires that entities recognize the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The income tax consequences on intra-entity transfers of inventory will continue to be deferred until the inventory has been sold to a third party. This guidance is effective for fiscal years beginning after December 15, 2017, which was the Company's first quarter of fiscal year 2018, and requires a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. Early adoption is permitted at the beginning of a fiscal year. The adoption of this guidance did not have a material impact on the consolidated financial statements or related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting", which provides clarification on accounting for modifications in share-based payment awards. This guidance is effective for fiscal years beginning after December 15, 2017, which was the Company's first quarter of fiscal year 2018, with early adoption permitted. The adoption of this guidance did not have an impact on the Company's consolidated financial statements or related disclosures.

Accounting Pronouncements Effective in Future Periods

In June 2018, the FASB issued ASU No. 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting", which expands guidance on accounting for share-

based payment awards, which includes share-based payment transactions for acquiring goods and services from nonemployees and aligns the accounting for share-based payments for employees and non-employees. This guidance is effective for annual periods beginning after December 15, 2018, with early adoption permitted. The guidance should be applied to new awards granted after the date of adoption. The adoption of this guidance is not expected to have an impact on the Company's consolidated financial statements or related disclosures unless there are grants of share-based payment awards.

Note 2. Property and Equipment

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

	December 31,	
	2018	**2017**
Research and development equipment	$ 885	$ 783
Computer hardware and software	811	545
Tools and molds	1,110	877
Leasehold improvements	1,500	297
Furniture and fixtures	462	181
	4,768	2,683
Less: accumulated depreciation and amortization	(1,984)	(1,153)
	$ 2,784	$ 1,530

Depreciation and amortization expense of property and equipment was $0.8 million and $0.6 million for the years ended December 31, 2018 and 2017, respectively.

Note 3. Intangible Asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The intangible asset was recorded at its fair value of $1.0 million at the date contributed in 2013, which is the gross carrying amount of the intangible asset at December 31, 2018 and 2017. Accumulated amortization of the intangible asset is $0.6 million and $0.5 million at December 31, 2018 and 2017, respectively. The Company recorded expense for the amortization of intangible assets of $0.1 million during the years ended December 31, 2018 and 2017. The estimated future amortization expense as of December 31, 2018, is as follows (in thousands):

2019	$	115
2020		115
2021		115
2022		81
	$	426

Note 4. Commitments

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. 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.

In November 2017, the Company entered into a new lease agreement (the “Lease”) with its current landlord, The Irvine Company, LLC, for the lease of approximately 25,548 square feet of office space of a building located in Irvine, California, which serves as its principal executive offices and includes general office, research and development, lab, and manufacturing spaces. The Company utilizes its old currently-leased space through the lease expiration date to conduct the training of its sales team.

Unless earlier terminated, the term of the Lease (the “Initial Term”) will expire on the final day of the calendar month following the seventh anniversary of the commencement date. The commencement date was set as August 2018. The Company did not control the leased premises before the commencement date. The aggregate base rent due over the Initial Term under the terms of the Lease is approximately $5.3 million (without giving effect to certain rent abatement terms). The Company is also responsible for the payment of additional rent to cover certain costs, taxes, and insurance. Based on the estimated monthly additional rent for 2018 as set forth in the Lease, the Company estimates that the additional rent during the Initial Term will be approximately $3.8 million. The Company also paid approximately $1.2 million for leasehold improvements, net of the tenant improvement allowance provided in the Lease of approximately $0.9 million.

The Company has a renewal option to extend the term of the Lease for a period of five years (the “Renewal Term”) 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.

At the commencement date of the Lease, the Company recorded an ROU asset of approximately $3.3 million and a lease liability of approximately $4.2 million on its consolidated balance sheet, calculated using the Initial Term of seven years. Total lease incentives excluded from the calculation of the ROU asset were approximately $0.9 million. As of December 31, 2018, the ROU asset has a balance of $3.1 million. The operating lease ROU asset is included within the Company’s other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company’s consolidated balance sheets. During the years ended December 31, 2018 and 2017, cash paid for amounts included in operating lease liabilities were $0.5 million and $0.2 million, respectively. Amortization of the ROU asset was $0.2 million for the year ended December 31, 2018. As of December 31, 2018 and 2017, the remaining lease term for all of the Company’s operating leases were 6.6 years and 1.8 years, respectively. The discount rate used to determine the present value of all of the Company’s operating leases’ future payments was 6.75%.

Rent expense for the years ended December 31, 2018 and 2017 was $0.7 million and $0.2 million, respectively.

Maturities of lease liabilities as of December 31, 2018, are as follows (in thousands):

2019	$	855
2020		703
2021		735
2022		768
2023		803
Thereafter		1,343
		5,207
Less: imputed interest		(1,158)
	$	4,049

License Agreement

In October 2013, the Company entered into the License Agreement with AMF, pursuant to which AMF agreed to license to 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"). Pursuant to the License Agreement, AMF granted to the Company a royalty-bearing, sublicensable (by written, executed agreements only, subject to the terms of the License Agreement) license under the AMF IP to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of (i) chronic pain in humans through the application of electrical energy to the nervous system, (ii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve, a nerve that interfaces with parasympathetic control of the heart, lungs and digestive tract, and (iii) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system. Pursuant to the License Agreement, the Company is obligated to pay a 4% royalty of all net revenue derived from the AMF Licensed Products 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, subject to certain adjustments. The initial term of the License Agreement is from October 1, 2013 to October 1, 2033, and will automatically continue until all patents are no longer in force. Beginning in 2018, the Company is required to pay a minimum annual royalty under the License Agreement. The minimum amount was $75,000 for 2018, with an increase in subsequent years of $25,000 (i.e., $100,000 for 2019) up to a maximum of $200,000 per year. The Company generated net revenue of $0.7 million and $0.1 million during the years ended December 31, 2018 and 2017, respectively, and recorded related royalties of $0.1 million during the year ended December 31, 2018. The Company recorded minimal related royalties during the year ended December 31, 2017.

Note 5. Long-Term Debt

In February 2018, the Company entered into the Loan and Security Agreement (the "Loan Agreement"), with Silicon Valley Bank, providing for a term loan (the "Term Loan"). Pursuant to the Loan Agreement, the Company may request up to $20.0 million in three tranches of term loans with such drawn obligations maturing on June 1, 2021. We requested $10.0 million from the first tranche ("Tranche A"), simultaneously with the entry into the Loan Agreement, which is currently outstanding. The Company may request (a) an additional $5.0 million ("Tranche B"), after the date commencing on the later of (i) the date that the Company achieves positive three-month results in the Company's ARTISAN-SNM pivotal study, as confirmed to Silicon Valley Bank by a member of the Company's management team and a member of its board of directors, and (ii) July 1, 2018, and ending on December 31, 2018 and (b) another $5.0 million ("Tranche C"), after the date commencing on the later of (i) the date that Silicon Valley Bank receives evidence, in form and substance reasonably satisfactory to Silicon Valley Bank, that the Company has received its pre-market approval ("PMA") in the United States for its r-SNM System or gross proceeds from the sale of its equity securities of not less than $20.0 million, and (ii) January 1, 2019, and ending on March 31, 2019, subject to certain terms and conditions. If either Tranche B or Tranche C is drawn, then the maturity of the Term Loan is automatically extended to December 1, 2021.

The Loan Agreement provides for monthly interest payments through December 31, 2018; provided that, (i) if the Company requests and Silicon Valley Bank funds Tranche B or Tranche C, this interest-only period automatically extends through June 30, 2019, and (ii) if the Company has received a PMA in the United States for its r-SNM System and the Company requests and Silicon Valley Bank funds Tranche C, the interest-only period automatically extends through December 31, 2019. On the first day of the end of the interest-only period, the Company will be required to repay the Term Loan in equal monthly installments of principal plus interest through maturity. Outstanding principal balances under the Term Loan bear interest at the prime rate plus 1.75%.

In October 2018, the Company and Silicon Valley Bank entered into an amendment to the Loan Agreement (the "Loan Amendment") in connection with which the Company requested the full $5.0 million from Tranche B and the full $5.0 million from Tranche C. The Company received the $10.0 million from both tranches in October 2018. Pursuant to the Loan Amendment, Silicon Valley Bank agreed to (i) extend the interest only period from June 30, 2019 to December 31, 2019, without requiring the receipt of the Company's PMA in the United States for the r-SNM System, and (ii) make Tranche C available immediately instead of January 1, 2019. In addition, pursuant to the Loan Amendment, Silicon Valley Bank added a fee of $100,000 in the event that the Company did not (i) consummate the IPO, with proceeds of no less than $75.0 million, (ii) receive PMA approval in the United States for the r-SNM System, or (iii) receive gross proceeds of at least $40.0 million from the sale of equity securities, in each case on or prior to June 30, 2019, which will not be owed since the Company completed the IPO offering in October 2018. In addition, as a result of the Company's request of the full $5.0 million from Tranche B and the full $5.0 million from Tranche C, the maturity of the Term Loan has been automatically extended to December 1, 2021. The transaction was accounted for as a debt modification. See Note 6 for discussion regarding stock warrants granted in connection with the Term Loan.

The Company may prepay amounts outstanding under the Term Loan in increments of $5.0 million at any time with 30 days prior written notice to Silicon Valley Bank. However, all prepayments of the Term Loan prior to maturity, whether voluntary or mandatory (acceleration or otherwise), are also subject to the payment of a prepayment fee equal to (i) for a prepayment made on or after the closing date through and including the first anniversary of the closing date, 3.00% of the principal amount of the Term Loan being prepaid, (ii) for a prepayment made after the date which is the first anniversary of the closing date through and including the second anniversary of the closing date, 2.00% of the principal amount of the Term Loan being prepaid, and (iii) for a prepayment made after the date which is the second anniversary of the closing date and before the maturity date, 1.00% of the principal amount of the Term Loan being prepaid. Additionally, on the earliest to occur of (i) the maturity date of the Term Loan, (ii) the acceleration of the Term Loan, or (iii) the prepayment of the Term Loan, the Company will be required to make a final payment equal to the original principal amount of such tranche multiplied by 7.50%. The Company is currently accruing the portion of the final payment calculated based on the amount outstanding under the Term Loan.

All obligations under the Term Loan are secured by a first priority lien on substantially all of the Company's assets, excluding intellectual property assets and more than 65% of the shares of voting capital stock of any of its foreign subsidiaries. The Company has agreed with Silicon Valley Bank not to encumber its intellectual property assets without Silicon Valley Bank's prior written consent unless a security interest in the underlying intellectual property is necessary

to have a security interest in the accounts and proceeds that are part of the assets securing the Term Loan, in which case the Company's intellectual property shall automatically be included within the assets securing the Term Loan. As of December 31, 2018, the Company is in compliance with all debt covenant requirements under the Term Loan.

The outstanding balance of the Term Loan at December 31, 2018 is $21.5 million, which is presented net of unamortized debt issuance costs of $2.0 million. As the Company has met conditions to draw Tranche C and therefore will not commence making monthly principal payments until January 2020, the outstanding balance of the Term Loan is classified in noncurrent liabilities at December 31, 2018.

Expected future principal payments for the term loan as of December 31, 2018, are as follows (in thousands):

2019	$ —
2020	9,688
2021	11,812
	$ 21,500

Note 6. Stockholders' Equity

Preferred Stock

Prior to the IPO, the Company had outstanding 12,219,315 shares of convertible preferred stock. Upon closing of the Company's IPO on October 31, 2018, all shares of outstanding convertible preferred stock were automatically converted to 15,813,297 shares of the Company's common stock. As of December 31, 2018, the Company is authorized to issue 10,000,000 shares of preferred stock with a par value of $0.0001 per share.

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 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, we 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 Option Plans

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. As of December 31, 2018 and 2017, a total of 3,178,593 and 2,652,903 shares have been reserved for issuance under the 2014 Plan, respectively. As of December 31, 2018 and 2017, there were 0 and 82,463 shares available for grant under the 2014 Plan, respectively. The 2018 Omnibus Incentive Plan was adopted upon our IPO and replaced the 2014 Stock Option Plan for future grants.

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 in order 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 4,540,019. As of December 31, 2018 there were 4,391,819 shares available for grant under the 2018 Plan.

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

	December 31,	
	2018	**2017**
Convertible preferred stock outstanding and issuable	—	13,079,920
Options outstanding under the 2014 Plan	1,416,147	903,857
Options remaining under the 2014 Plan for future issuance	—	82,463
Options and restricted shares outstanding under the 2018 Plan	148,200	—
Options and restricted shares remaining under the 2018 Plan for future issuance	4,391,819	—
	5,956,166	14,066,240

Preferred Stock outstanding and issuable at December 31, 2017 includes shares of the Company and shares in Axonics Europe, S.A.S., which were exchangeable for the applicable series of Preferred Stock pursuant to the Share Exchange Agreement. Immediately prior to the completion of our IPO, all of the shares in Axonics Europe, S.A.S. were exchanged into shares of the respective class of Preferred Stock.

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 actually become exercisable. The expense for options granted to nonemployees is recognized based upon the fair value of the options as the options vest.

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

	Years Ended December 31,	
	2018	2017
General and administrative	$ 361	$ 268
Research and development	197	179
Sales and marketing	48	14
	$ 606	$ 461

Valuation Assumptions – Restricted Stock and Stock Options

The grant-date fair value per share for restricted stock awards issued under the 2018 Plan was based upon the closing market price of our common stock on the award grant-date.

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,	
	2018	2017
Expected term (in years)	5.00 - 6.96	5.00 - 6.50
Stock volatility	68.04% - 77.03%	70.61% - 76.01%
Risk-free interest rate	2.26% - 3.07%	1.82% - 2.11%
Dividend rate	—	—

The Company used the simplified method of determining the expected term of stock options. 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. The weighted-average grant date fair value of options granted was $3.62 and $0.88 for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018 and 2017, there was $2.6 million and $0.9 million, respectively, of total unrecognized compensation cost related to non-vested stock options and restricted shares that is expected to be recognized over a weighted-average period of approximately 2.7 and 2.9 years, respectively.

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, 2016	476,451	$ 0.98	
Options granted	896,828	1.36	
Options exercised	(446,971)	1.33	$ 13 (1)
Options forfeited	(22,451)	0.97	
Outstanding at December 31, 2017	903,857	1.18	
Options granted	668,380	3.55	
Options exercised	(55,840)	1.47	$ 23 (1)
Options forfeited	(2,050)	1.23	
Outstanding at December 31, 2018	1,514,347	$ 2.22	$ 19,527 (2)
Options exercisable at December 31, 2018	1,109,167	$ 1.33	$ 15,281 (2)

(1) Represents the total difference between our 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 our closing stock price on the last trading day of 2018 and the stock option exercise price, multiplied by the number of in-the-money options as of December 31, 2018. The amount of intrinsic value will change based on the fair market value of our stock.

The weighted-average remaining contractual term of options outstanding and exercisable is 8.4 years and 8.7 years at December 31, 2018 and 2017, respectively.

There were 50,000 restricted stock awards granted during the year ended December 31, 2018, and none were vested or forfeited. There were no restricted stock awards granted during the year ended December 31, 2017.

Stock Subscriptions Receivable

As of December 31, 2017 and throughout 2018, several members of management of the Company exercised stock options covering 1,685,597 shares of common stock, in exchange for promissory notes with a principal balance of $1.8 million. These promissory notes bore interest at a rate of 4.5% per annum and were due in full in 2020 to 2022. The promissory notes could have become due earlier if the shares of common stock received from the option exercises are sold, the employee terminates employment with the Company, or pursuant to other provisions specified in the notes. The notes were secured by the shares of common stock received from the option exercises. On October 4, 2018, the Company entered into agreements with each noteholder to terminate each of their respective promissory notes and to forgive all respective obligations for payment thereof in connection with the Company's IPO. As a result, on October 4, 2018, the Company forgave all outstanding stock subscriptions receivable referenced above in the aggregate amount of $1.8 million plus accrued interest, which amount was recorded as compensation expense.

Stock Warrants

In February 2018, in connection with the Company's entry into the Loan Agreement (as defined below), the Company issued warrants to Silicon Valley Bank and Life Science Loans II, LLC, its counterparty. Each warrant entitles the holder thereof to purchase up to 33,333 shares of the Series C Preferred Stock at an exercise price of $9.00 per share. Initially, each warrant was exercisable for 16,667 shares of Series C Preferred Stock. In connection with the Term Loan Amendment in October 2018, the Company drew on Tranche B and C, and an additional 16,666 shares became exercisable under each warrant. Each warrant will expire on February 6, 2028. In connection with the IPO, the Company's outstanding warrants to purchase shares of Series C convertible Preferred Stock were automatically converted into warrants to purchase up to an aggregate of 80,000 shares of common stock at an exercise price of $7.50 per share.

In 2018 and prior to the IPO, warrants to purchase 66,666 shares of the Company's Series C Preferred Stock were outstanding and are considered liabilities, the value of which is recorded in current liabilities and was adjusted to fair value at each reporting period with the change reflected in the statements of comprehensive loss. The fair value of the warrants in 2018 at grant date and prior to the IPO approximated $1.0 million using the Black-Scholes option pricing model with the following assumptions: expected life of 10 years, risk-free interest rate of 2.5% and stock volatility of 68.5%. The values of the warrants are accounted for as deferred loan costs and amortized to interest expense on an effective interest method. In connection with the Company's IPO, the conversion of preferred stock into common stock, and the conversion of the warrants to purchase Series C preferred stock into warrants to purchase common stock, the warrant liability of $1.0 million was reclassified to additional paid-in-capital. The change in fair value of the warrants in 2018 prior to their conversion to permanent equity totaled $0.3 million, which is recorded in interest and other expense.

Note 7. Noncontrolling Interest

For less-than-wholly-owned consolidated subsidiaries, noncontrolling interest is the portion of equity not attributable, directly or indirectly, to the Company. The Company evaluates whether noncontrolling interests possess any redemption features outside of the Company's control. If such features are determined to exist, the noncontrolling interests are presented outside of permanent equity on our consolidated balance sheets within mezzanine equity.

Prior to the Company's IPO, the Company's noncontrolling interest related to the portion of Axonics Europe S.A.S. not owned by the Company. The Company presented noncontrolling interest as mezzanine equity on the consolidated balance sheet at December 31, 2017 due to the Share Exchange Agreement that provided the holders of the equity in Axonics Europe S.A.S. (excluding the Company) the unilateral right to exchange its equity interest in Axonics Europe S.A.S. for Preferred Stock of the Company at any time. The Company's Preferred Stock was presented as mezzanine equity at December 31, 2017, and as such, the rights under the Share Exchange Agreement required the noncontrolling interest to be presented as mezzanine equity as well.

Prior to the Company's IPO, the comprehensive loss attributable to the noncontrolling interest in Axonics Europe S.A.S. were absorbed by the Company since the investors are protected from any losses in this entity due to the conversion right. Changes in amounts attributable to the redeemable noncontrolling interest were presented in the Company's consolidated statements of mezzanine equity during the year ended December 31, 2017.

In conjunction with the Company's IPO, the interests held by the other investors in Axonics Europe S.A.S. were converted into a fixed number of shares of the Company's preferred stock pursuant to the terms of the Share Exchange Agreement. These preferred stock shares were then automatically converted into 4,221,715 shares of common stock, and as such, Axonics Europe S.A.S. is the Company's wholly-owned subsidiary at December 31, 2018.

Note 8. Income Taxes

The Company's effective tax rate of approximately 0% differs from the federal statutory tax rate due primarily to providing a full valuation allowance on deferred tax assets.

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 net deferred tax assets are as follows (in thousands) as of:

	December 31,	
	2018	2017
Compensation accruals	$ 154	$ 101
Depreciation and amortization	(399)	(37)
Lease liability	262	22
Net operating loss carryforwards	26,627	18,250
R&D tax credit carryforwards	1,582	1,425
Other	436	17
Total deferred tax assets	28,662	19,778
Less: valuation allowance	(28,662)	(19,778)
Total net deferred tax assets	$ —	$ —

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law in the United States. Among other items, the Tax Act reduces the federal corporate tax rate to 21% from the existing maximum rate of 35%, effective January 1, 2018. As a result, the Company revalued its net deferred tax asset at the new lower tax rate at December 31, 2017. The Company did not have any Global Intangible Low-taxed Income ("GILTI") adjustments, as foreign losses were minimal during the years ended December 31, 2018 and 2017. At December 31, 2018, the Company had federal and California net operating loss ("NOL") carryforwards of approximately $63.4 million. 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 has not performed an analysis of changes in ownership for purposes of these Internal Revenue Code sections. Ownership changes could impact the Company's ability to utilize NOL carryforwards remaining at an ownership change date. Under the Tax Act, post-2017 NOLs can be carried forward indefinitely and the annual limit of deduction equals 80% of taxable income. NOLs expire between 2034 and 2038. At December 31, 2018, the Company also had research and development tax credit carryforwards of approximately $2.3 million, which will expire in 2036 to 2038. Approximately $0.6 million and $0.5 million of these research and development tax credit carryforwards are included in prepaid expenses and other current assets on the Company's consolidated balance sheets at December 31, 2018 and 2017, respectively, as they are expected to be utilized in 2019 as a credit to offset payroll taxes. The remaining amount of research and development tax credit carryforwards are included in net deferred tax assets. Income tax expense, consisting of state income taxes in California, were minimal during the years ended December 31, 2018 and 2017.

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

	Years Ended December 31,	
	2018	2017
Tax at statutory federal rate	21.0 %	34.0 %
State tax, net of federal benefit	7.0 %	5.8 %
Excess tax benefits related to stock-based compensation	(0.4)%	(1.0)%
Effect of Tax Cuts and Jobs Act of 2017	— %	(37.5)%
Change in valuation allowance	(27.4)%	2.4 %
Other	(0.2)%	(3.7)%
Effective tax rate	— %	— %

Note 9. 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 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, 2018 and 2017, the Company contributions to the plan amounted to $0.3 million and $0.2 million, respectively.

Note 10. Related Party Transactions

The Company has a License Agreement and corresponding royalties incurred with a shareholder. A former member of our board of directors is the President, Chief Executive Officer, Senior Vice President, Business Development, and General Counsel of this entity. For additional information, see Note 4.

The Company incurred $0.1 million during each of the years ended December 31, 2018 and 2017 to a scientific advisor who is also a non-management stockholder of the Company. Amounts payable to this advisor were minimal at December 31, 2018 and 2017.

The Company incurred $0.3 million and $0.1 million during the years ended December 31, 2018 and 2017, respectively, for engineering and design services to a company that is owned by a non-management stockholder of the Company. Amounts payable to this company were minimal at December 31, 2018. There were no amounts payable to this company at December 31, 2017.

The 2014 Plan allowed for certain members of management to purchase vested options and unvested options (subject to repurchase rights) through a full recourse promissory note and stock pledge agreement. The promissory notes outstanding were recorded as “Stock subscriptions receivable” in the accompanying consolidated balance sheet. On October 4, 2018, the Company entered into agreements with certain officers and directors to terminate each of their respective promissory notes and to forgive all respective obligations for payment thereof in connection with the Company’s IPO. As a result, on October 4, 2018, the Company forgave all outstanding stock subscriptions receivable referenced above in the aggregate amount of $1.8 million plus accrued interest, which amount was recorded as compensation expense.

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

On August 29, 2018, we dismissed Peterson Sullivan LLP, or Peterson Sullivan, as our independent registered public accounting firm. This dismissal has been ratified by the audit committee of our board of directors. Peterson Sullivan audited our consolidated financial statements for the years ended December 31, 2017 and 2016. The audit report issued by Peterson Sullivan on June 15, 2018, did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope, or accounting principles. Peterson Sullivan did not provide an audit opinion on our consolidated financial statements for any period subsequent to the year ended December 31, 2017.

During the years ended December 31, 2017 and 2016, and the subsequent interim period through August 29, 2018, (i) there were no disagreements between us and Peterson Sullivan (as that term is defined in Item 304(a)(1)(iv) of Regulation S-K) on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Peterson Sullivan, would have caused them to make reference to the subject matter of the disagreements in connection with their report on the financial statements for such year, and (ii) there were no reportable events as such term is defined in Item 304(a)(1)(v) of Regulation S-K.

On August 31, 2018, we engaged BDO USA, LLP (“BDO”), as our independent registered public accounting firm, which engagement has been ratified by the audit committee of our board of directors. During the fiscal years ended December 31, 2017 and 2016 and the subsequent interim period through August 31, 2018, we (or any person on our behalf) did not consult with BDO regarding any of the matters described in Items 304(a)(2)(i) or 304(a)(2)(ii) of Regulation S-K.

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, 2018, 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 effective at the reasonable assurance level as of December 31, 2018.

Management’s Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies. Further, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting as long as we are an “emerging growth company” pursuant to the provisions of the JOBS Act.

Changes in internal control over financial reporting

Other than the remediation efforts identified below to remediate the material weakness disclosed in the Amendment No. 2 to the Form S-1, 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.

Remediation of Material Weakness in Internal Control Over Financial Reporting

Management has implemented remediation measures related to analyzing accounting and reporting for complex financial instruments and consolidation matters. We have and will continue to supplement the accounting and finance function with additional subject matter expertise on complex accounting matters, and have enhanced the internal control environment to ensure supplemental procedures to review and ensure the adequacy of our review and documentation of complex transactions.

We believe these measures have remediated the material weakness as of December 31, 2018.

Item 9B. Other Information.

None.

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, 2018 and delivered to stockholders in connection with our 2019 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, 2018 and delivered to stockholders in connection with our 2019 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, 2018 and delivered to stockholders in connection with our 2019 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, 2018 and delivered to stockholders in connection with our 2019 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, 2018 and delivered to stockholders in connection with our 2019 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:

Reference is made to the Index to consolidated financial statements of Axonics Modulation Technologies, Inc. under Item 8 of Part II hereof.

2. Financial Statement Schedule:

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:

See Exhibit Index immediately following the signature page of this Form 10-K.

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 MODULATION TECHNOLOGIES, INC.

Date: March 5, 2019

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 Danny L. Dearen 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: March 5, 2019	By:	/s/ Raymond W. Cohen
		Raymond W. Cohen
		Chief Executive Officer and Director
		(Principal Executive Officer)
Date: March 5, 2019	By:	/s/ Danny L. Dearen
		Danny L. Dearen
		President and Chief Financial Officer
		(Principal Financial and Accounting Officer)
Date: March 5, 2019	By:	/s/ Raphaël Wisniewski
		Raphaël Wisniewski
		Chairman of the Board and Director
Date: March 5, 2019	By:	/s/ Erik Amble, Ph.D.
		Erik Amble, Ph.D.
		Director
Date: March 5, 2019	By:	/s/ Geoff Pardo
		Geoff Pardo
		Director
Date: March 5, 2019	By:	/s/ Shahzad Malik, M.B. BChir
		Shahzad Malik, M.B. BChir
		Director
Date: March 5, 2019	By:	/s/ Juliet Tammenoms Bakker
		Juliet Tammenoms Bakker
		Director
Date: March 5, 2019	By:	/s/ Robert E. McNamara
		Robert E. McNamara
		Director
Date: March 5, 2019	By:	/s/ Michael H. Carrel
		Michael H. Carrel
		Director

EXHIBIT INDEX

Exhibit Number	Exhibit Title	Incorporated by Reference				Filed Herewith (X)
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-38721	3.1	11/05/2018	
3.2	Amended and Restated Bylaws.	8-K	001-38721	3.2	11/05/2018	
4.1	Specimen certificate evidencing shares of common stock of the Registrant.	S-1	333-227732	4.1	10/5/2018	
4.2	Fourth Amended and Restated Investors' Rights Agreement, dated March 29, 2018, by and among the Registrant and the Investors party thereto.	S-1	333-227732	4.2	10/5/2018	
4.3	Amendment to Fourth Amended and Restated Investors' Rights Agreement, dated October 17, 2018, by and among the Registrant and the Investors party thereto.	S-1/A	333-227732	4.3	10/22/2018	
4.4	Warrant to Purchase Series C preferred stock, dated February 6, 2018, issued by the Registrant to Silicon Valley Bank.	S-1	333-227732	4.3	10/5/2018	
4.5	Warrant to Purchase Series C preferred stock, dated February 6, 2018, issued by the Registrant to Life Science Loans II, LLC.	S-1	333-227732	4.4	10/5/2018	
10.1+	2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.8	10/22/2018	
10.2+	Form of Option Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.9	10/22/2018	
10.3+	Form of Restricted Shares Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.10	10/22/2018	
10.4+	Form of RSU Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.11	10/22/2018	
10.5+#	Form of Debt Forgiveness Agreement and Cancellation of Note (Tax Withholding-Shares).	S-1	333-227732	10.28	10/5/2018	
10.6+#	Form of Debt Forgiveness Agreement and Cancellation of Note (Tax Withholding-Cash).	S-1	333-227732	10.29	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	

21.1	List of Subsidiaries	X
23.1	Consent of Independent Registered Public Accounting Firm	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
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.

** 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.

Exhibit 21.1

List of Subsidiaries of
Axonics Modulation Technologies, 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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Axonics Modulation Technologies, Inc.
Irvine, California

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No.333-228170) of Axonics Modulation Technologies, Inc. of our report dated March 5, 2019, relating to the consolidated financial statements which appears in this Form 10-K.

/s/ BDO USA, LLP
Costa Mesa, California

March 5, 2019

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 Modulation Technologies, 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) [Omitted pursuant to Exchange Act Rules 13a-14(a) and 15d-15(a)];

   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: March 5, 2019

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, Danny L. Dearen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Axonics Modulation Technologies, 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) [Omitted pursuant to Exchange Act Rules 13a-14(a) and 15d-15(a)];

   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: March 5, 2019

By: /s/ Danny L. Dearen

Danny L. Dearen

President and 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 Modulation Technologies, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2018 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: March 5, 2019

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 Modulation Technologies, Inc. and will be retained by Axonics Modulation Technologies, 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 Modulation Technologies, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2018 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: March 5, 2019

By: /s/ Danny L. Dearen

Danny L. Dearen

President and Chief Financial Officer

(Principal Financial Officer)

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