Filed Pursuant to Rule 424(b)(5)
Registration No. 333-234546

The information in this prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This prospectus supplement is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 19, 2019

PROSPECTUS SUPPLEMENT
(to prospectus dated November 18, 2019)

$110,000,000

Axonics Modulation Technologies, Inc.

Common Stock

We are selling $100,000,000 of shares of our common stock, and the selling stockholders identified in this prospectus supplement are selling $10,000,000 of shares of our common stock. We will not receive any proceeds from the sale of any shares by the selling stockholders.

Our common stock trades on the Nasdaq Global Select Market, or Nasdaq, under the trading symbol "AXNX." On November 18, 2019, the last reported sale price of our common stock on Nasdaq was $23.43 per share.

We are an "emerging growth company" under the federal securities laws and, as such, are subject to reduced public company reporting requirements. See "Prospectus Supplement Summary—Implications of Being an Emerging Growth Company."

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page S-7 of this prospectus supplement and the risk factors included in the accompanying base prospectus and in the documents filed with the U.S. Securities and Exchange Commission, or the SEC, and incorporated by reference herein and therein to read about certain factors you should consider before investing in our common stock.

	Per Share	Total
Public offering price	$	$
Underwriting discount(1)	$	$
Proceeds, before expenses, to us	$	$
Proceeds, before expenses, to the selling stockholders	$	$

(1) We refer you to "Underwriting" beginning on page S-64 for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase an additional $16,500,000 of shares of our common stock from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus supplement.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about November , 2019.

BofA Securities Barclays

Wells Fargo Securities

The date of this prospectus supplement is November , 2019.

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We, the selling stockholders and the underwriters have not authorized anyone to provide any information or to make any representations other than those contained or incorporated by reference into this prospectus supplement, the accompanying prospectus or in any free writing prospectus prepared by or on behalf of us. We, the selling stockholders, and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus supplement is an offer to sell only the shares offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus supplement, the accompanying prospectus, the documents incorporated herein by reference or in any applicable free writing prospectus is current only as of the date of the applicable document, regardless of its time of delivery or any sale of shares of our

common stock. Our business, financial condition, results of operations and prospects may have changed since those dates.

For investors outside the United States: We, the selling stockholders, and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus supplement or the accompanying prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus supplement or the accompanying prospectus must inform themselves, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States.

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the U.S. Securities and Exchange Commission, or the SEC, utilizing a "shelf" registration process. This document is in two parts. The first part is this prospectus supplement, which describes the terms of the offering of the common stock offered hereby and also adds to and updates the information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part is the accompanying prospectus dated November 18, 2019 (included in our registration statement on Form S-3 (File No. 333-234546)), which provides more general information, some of which may not apply to this offering and some of which may have been supplemented or superseded by information in this prospectus supplement or documents incorporated or deemed to be incorporated by reference into this prospectus supplement that we filed with the SEC subsequent to the date of the prospectus. To the extent that there is any conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference herein or therein, on the other hand, you should rely on the information in this prospectus supplement.

You should read this prospectus supplement, the accompanying prospectus and any free writing prospectus to which we have referred you and the documents incorporated by reference herein described under "Where You Can Find Additional Information" and "Incorporation of Certain Information by Reference" in this prospectus supplement before deciding whether to invest in the shares of common stock offered by this prospectus supplement.

You should not consider any information in this prospectus supplement, the accompanying prospectus or any free writing prospectus to which we have referred you to be investment, legal or tax advice. You should consult your own counsel, accountants and other advisors for legal, tax, business, financial and related advice regarding the purchase of any of the shares of common stock offered hereby.

This prospectus supplement 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 prospectus supplement also includes trademarks and trade names that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this prospectus supplement 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.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere in this prospectus supplement and the accompanying prospectus, and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider in making your investment decision. You should read the entire prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus carefully before making an investment in our common stock. You should carefully consider, among other things, our financial statements and related notes incorporated by reference into this prospectus supplement and the accompanying prospectus from our Annual Report on Form 10-K for the year ended December 31, 2018, or our 2018 Annual Report, our Quarterly Report on Form 10-Q for the period ended September 30, 2019, or our 2019 Q3 Quarterly Report, and the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2018 Annual Report and 2019 Q3 Quarterly Report and incorporated by reference into this prospectus supplement and the accompanying prospectus. Unless the context requires otherwise, references in this prospectus supplement and the accompanying prospectus to "Axonics," "our company," "we," "us" and "our" refer to Axonics Modulation Technologies, Inc. and its consolidated subsidiaries.

Our Business

We are a medical technology company that has developed and is commercializing an innovative and minimally invasive implantable neurostimulation system for sacral neuromodulation, or SNM, therapy. SNM therapy is primarily used to treat patients with urinary urge incontinence, or UUI, and urinary urgency frequency, or UUF, together referred to as overactive bladder, or OAB, fecal incontinence, or FI, and non-obstructive urinary retention, or UR. We believe our proprietary SNM system, or our r-SNM System, has the potential to disrupt and grow the approximately $650 million, as of 2018, global SNM market, which is currently served by Medtronic plc, or Medtronic, as a single participant.

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 bladder and bowel dysfunction. We believe our proprietary r-SNM System offers significant advantages, including being the first and only FDA-approved rechargeable SNM system that is designed to last approximately 15 years, and is 60% smaller than the InterStim II System, or InterStim II, which is the only other approved SNM product and is marketed by Medtronic.

Our r-SNM System received premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, on September 6, 2019 for the treatment of FI, and on November 13, 2019 for the treatment of OAB and UR. We also have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR.

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

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

- The study has passed the six-month primary endpoint and completed one-year follow up;
- 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 one year, 115 of the 129 implanted patients, or 89%, continued to be therapy responders;
- At six months, 93% of all implanted patients reported being "satisfied" with the therapy, and at one year, 93% of all implanted patients continued to report being "satisfied" with the therapy; and
- No serious device-related adverse events have been reported.

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

- The study has completed one-year follow-ups and two-year follow-ups;
- 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;
- At 12 months, 84% of test responders and 77% of all implanted patients were “very” or “moderately” satisfied with the therapy provided by our r-SNM System; and
- No serious device-related adverse events have been reported.

We believe that our r-SNM System offers similar therapeutic benefits and competitive advantages to the only currently available SNM technology, InterStim II, offered by Medtronic. We believe that our r-SNM System is the first and only FDA-approved system for SNM therapy with a rechargeable implantable neurostimulator, or 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. We also received CE Mark for our r-SNM System for 1.5T/3.0T MRI full-body conditional labeling on February 22, 2019 and FDA approval for our r-SNM System for 1.5T MRI full-body and 3.0T head conditional labeling on September 6, 2019. Our r-SNM System allows full-body MRI scans and head scans under certain conditions, 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 a body part other than the head, which is currently required for patients implanted with InterStim II. This full-body MRI 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, we believe that 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 to fabricate 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, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, 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 clinician programmer that guides the implanting physician through electrode placement and stimulation programming.

Recent Developments

On November 13, 2019, our PMA application for our r-SNM System for the treatment of OAB and UR was approved by the FDA.

On November 4, 2019, certain affiliates of Medtronic filed a lawsuit against us in the United States District Court for the Central District of California. The lawsuit asserts that our r-SNM System infringes certain patents owned by these affiliates of Medtronic and seeks customary remedies for patent infringement, including damages (including treble damages), an injunction and attorneys’ fees. We intend to vigorously defend against these claims. For important further information about this lawsuit. See “Risk Factors— Risks Related to Intellectual Property—Litigation or other proceedings or third-party claims of intellectual property infringement against us, including the

Medtronic Litigation, or any of our current or future licensors, including AMF, could require us to spend significant time and money and could prevent us from selling our r-SNM System, or affect our stock price" in this prospectus supplement.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public 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 of 2002, as amended, or 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.

In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected not to take advantage of this transition period. We will remain an emerging growth company until the earliest of (i) December 31, 2023, (ii) the first fiscal year after our annual gross revenues exceed $1.07 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year.

Corporate 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. 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 prospectus supplement, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus supplement or in deciding whether to purchase our securities.

THE OFFERING

The following is a brief summary of certain terms of this offering. For a more complete description of the terms of the common stock offered hereby, see the "Description of Capital Stock" section of the accompanying prospectus.

Common stock offered by us	$100,000,000 of shares of our common stock.
Common stock offered by the selling stockholders	$10,000,000 of shares of our common stock.
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to an additional $16,500,000 of our common stock at the public offering price less underwriting discounts and commissions.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately million (or approximately $ million if the underwriters exercise their option to purchase additional shares in full), based on the public offering price of $ per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering (i) to support the commercial launch of our r-SNM System in the United States, Europe and Canada, (ii) to conduct SNM-related research and development activities and to fund the technological enhancement of our r-SNM System, and (iii) for working capital and general corporate purposes. In addition, the selling stockholders are selling shares of our common stock in this offering and we will not receive any of the proceeds from the shares sold by the selling stockholders. See "Use of Proceeds" for more information.
Risk factors	Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page S-7 of this prospectus supplement and the risk factors included in the accompanying base prospectus and in the documents incorporated by reference herein and therein to read about certain factors you should consider before investing in our common stock.
Nasdaq Global Select Market symbol	"AXNX"

The number of shares of our common stock to be outstanding after this offering is based on 28,633,911 shares of our common stock outstanding as of September 30, 2019, and excludes as of that date:

- 1,146,738 shares of our common stock issuable upon the exercise of outstanding stock options under our 2014 Stock Incentive Plan, as amended, or the 2014 Plan, at a weighted-average exercise price of $1.40 per share, and 1,485,028 shares of our common stock issuable upon the exercise of outstanding stock options under our 2018 Omnibus Incentive Plan, or the 2018 Plan, at a weighted-average exercise price of $20.15 per share;

- 92,672 shares of our common stock issuable upon the vesting and settlement of restricted stock units outstanding under the 2018 Plan; and
- 2,447,071 shares of our common stock reserved for future issuance under the 2018 Plan.

Unless otherwise indicated, all information contained in this prospectus supplement assumes:

- no exercise by the underwriters of their option to purchase an additional $16,500,000 of our common stock from us; and
- no exercise of the outstanding stock options and warrants and no settlement of the restricted stock units described above.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the following information about these risks, as well as the information set forth under the heading "Risk Factors" in our 2018 Annual Report, together with the other information appearing elsewhere in this prospectus or any prospectus supplement or incorporated by reference in this prospectus supplement, including our consolidated financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in each of our 2018 Annual Report and the 2019 Q3 Quarterly Report, before deciding to invest in our securities. The occurrence of any of these risks could have a material and adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Business and Strategy

We have derived minimal revenue from our operations and incurred significant operating losses since inception, and we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.

We are a medical technology company with a limited operating history. To date, we have invested substantially all of our efforts in the research and development of, seeking regulatory approval for, and commercialization of our 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.

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, for the years ended December 31, 2018 and 2017, we have recorded net losses of $32.5 million and $18.1 million, respectively, and for the unaudited nine months ended September 30, 2019 and 2018, we have recorded net losses of $57.2 million and $22.8 million, respectively. As of September 30, 2019, we had an accumulated deficit of $156.8 million (unaudited). To date, we have financed our operations through equity financings, including our initial public offering, and amounts borrowed under the Loan Agreement (as 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.

We expect that our operating expenses will continue to increase as we (i) continue to build our commercial infrastructure, (ii) develop, enhance, and begin to commercialize our r-SNM System in the United States, (iii) potentially seek additional FDA regulatory approvals for our r-SNM System or other future product candidates in the United States, (iv) increase our commercialization efforts internationally and (v) incur additional operational costs associated with being a public company. For example, we hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States and expect to grow our sales force over time. As we commercialize our r-SNM System, we may need to pay our U.S. sales team increased compensation in the form of product sales commissions, which will increase our operating expenses. 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.

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:

- the effectiveness of our marketing and sales efforts in the United States and internationally;
- our success in educating physicians and patients about the benefits, administration and use of our r-SNM System;
- the acceptance by physicians and patients of the safety and effectiveness of our r-SNM System;
- our third-party manufacturers' and suppliers' ability to manufacture and supply the components of our r-SNM System in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements, and to remain in good standing with regulatory agencies;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing therapies;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to our 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 raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our r-SNM System; and
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our r-SNM System.

We began marketing and selling our r-SNM System in certain limited European markets in 2018 through a limited direct sales force that targets physicians and hospitals. In the United States, we began marketing and selling our r-SNM System in the fourth quarter of 2019 through our dedicated direct sales organization. As a result, we have limited experience marketing and selling our r-SNM System.

We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. However, we expect that our sales force will 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 our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent any of our sales force is comprised of personnel hired from our competitor, we may have to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. This may subject us to allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Addressing such allegations would be costly both in terms of time and resources. Any of these risks may adversely affect our business.

We 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, conducting clinical studies for our r-SNM System, and building our dedicated direct sales organization. We expect that certain of these activities and the associated expenses will continue. Our expenses

have also increased substantially in connection with the commercialization of our r-SNM System in the United States, including hiring qualified personnel and retaining our sales team. Additional expenditures also include costs associated with manufacturing and supply, sales and marketing costs, costs and expenses incidental to being a public company, and general operations. In addition, other unanticipated costs may arise.

As of September 30, 2019, we had cash and cash equivalents of $76.2 million and short-term investments of $25.3 million.

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

- the costs associated with manufacturing, selling, and marketing our r-SNM System in the United States, including the cost and timing of implementing our sales and marketing plan and expanding our manufacturing capabilities;
- our ability to retain and compensate the highly qualified personnel necessary to execute our plans;
- our ability to effectively market and sell, and achieve sufficient market acceptance and market share for, our r-SNM System;
- the costs to maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights, including the Medtronic Litigation;
- 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 postmarket 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 and reporting systems, incidental to being a public company.

We may need to raise additional capital, and if we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our 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 compete against other companies offering first-, second- and third-line therapies for the treatment of OAB, including Medtronic, 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 other implantable SNM devices. We face competition from major medical device companies worldwide, including Medtronic, the maker of InterStim II. InterStim II is currently the only other implantable SNM device approved for commercial sale in the United States by the FDA. However, in October 2019, Medtronic announced it has filed a pre-market approval supplement, or PMA, with the FDA for approval of a new neurostimulation device and leads. According to Medtronic, the new device is a rechargeable, implantable SNM device to treat the same patient population as is treated by Interstim II. Medtronic claims that the new device is designed to be smaller and to facilitate MRI conditional labeling, and Medtronic is seeking FDA approval for a claim of a 15-year life in the body. The new device is not currently approved by the FDA. Medtronic has predicted that its PMA will undergo a 180-day review process with the FDA, and if approved in this timeframe, could potentially position the new device to be available in the spring of 2020. If approved, these new offerings could significantly impact the competitive landscape and our ability to capture and penetrate market share in the third-line therapy treatment market, and therefore could potentially have a material adverse effect on our business, financial condition and results of operation.

We also compete with other less invasive third-line treatments, such as BOTOX injections, a product sold by Allergan plc, PTNS, as well as more invasive surgical treatment options, and drugs for the treatment of OAB and FI. In addition, emerging businesses may be in the early stages of developing additional SNM devices or therapies designed to treat OAB or FI. Many of these companies have longer, more established operating histories and significantly greater financial, technical, marketing, sales, distribution and other resources than we do. We face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States. If one or more device manufacturers successfully develops a device that is more effective, better tolerated or otherwise results in a better patient experience, or if improvements in other third-line therapies make them more effective, easier to use or otherwise more attractive than our therapy, our ability to penetrate the third-line segment of the treatment market or maintain market share could be significantly and adversely affected, which would have a material adverse effect on our business, financial condition and results of operations.

Our overall competitive position is dependent upon a number of factors, including:

- company, product, and brand recognition;
- history of product use and physician familiarity with products and treatments;
- regulatory approvals;
- product safety, reliability and durability;
- INS size, rechargeability and battery life;
- quality and volume of clinical data;
- effective marketing to and education of patients, physicians and hospitals;
- product ease of use and patient comfort;
- physician implantation and programming process;
- sales force experience and market access;
- product support and service;
- technological innovation, product enhancements, and speed of innovation;
- pricing and revenue strategies;
- procedure costs to patients and the overall healthcare system; and
- dedicated practice development.

In addition to existing competitors, other larger and more established companies may acquire or in-license competitive products and could directly compete with us. These competitors may also try to compete with our 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. See "Risks Related to Intellectual Property—Litigation or other proceedings or third-party claims of intellectual property infringement against us, including the Medtronic Litigation, or any of our current or future licensors, including AMF, could require us to spend significant time and money and could prevent us from selling our r-SNM System, or affect our stock price." Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. As more companies develop new intellectual property in our market, there is the possibility of a competitor acquiring patents or other rights that may limit our ability to update our technologies and products which may impact demand for our 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 approved and 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 to fabricate 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 which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, 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, full-body MRI conditional labeling, and an easy-to-use patient remote control. Finally, we designed and custom built a 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. In addition, as discussed above, in October 2019, Medtronic announced it has filed a PMA with the FDA for approval of a new neurostimulation device and leads. According to Medtronic, the new device is a rechargeable, implantable SNM device to treat the same patient population as is treated by Interstim II. Medtronic claims that the new device is designed to be smaller and to facilitate MRI conditional labeling, and Medtronic is seeking FDA approval for a claim of a 15-year life in the body. The new device is not currently approved by the FDA. Medtronic has predicted that its PMA will undergo a 180-day review process with the FDA, and if approved in this timeframe, could potentially position the new device to be available in the spring of 2020. If approved, these new offerings could significantly impact the competitive landscape and our ability to capture and penetrate market share in the third-line therapy treatment market, and therefore could potentially have a material adverse effect on our business, financial condition and results of operation. We may also 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 other devices, 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.

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 manufacturers 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, or 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 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.

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 depend on single source suppliers to manufacture certain of our components, sub-assemblies and materials, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition and results of operations.

We rely on single source suppliers in many instances for certain of the components, sub-assemblies and materials for our products. These components, sub-assemblies and materials are critical and there are relatively few alternative sources of supply. We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies and materials, and in some instances we do not carry a

significant inventory of these items. While we believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that we would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses.

Our dependence on third-party suppliers subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the laws and regulations enforced by the FDA and state regulatory authorities;
- inability to ensure the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the FDA's Quality Regulation System, or QSR, and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner.

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 us 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) bladder and bowel 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. We have the right to expand the field of use for the AMF Licensed Products to the 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.

The license is co-exclusive with AMF solely with respect to (i) AMF IP resulting from AMF's performance of any engineering services rendered under the License Agreement, and (ii) AMF's right to use AMF IP for non-commercial research, educational and scholarly purposes.

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, or 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. Any and all improvements to AMF IP made by us will be owned by AMF and licensed to us under the License Agreement. As of the date of this prospectus supplement, 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, or 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 a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (i) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products and (b) a minimum annual royalty, or the Minimum Royalty, payable quarterly. The Minimum Royalty will automatically increase each year after 2018, subject to a maximum amount of $200,000 per year. During the nine months ended September 30, 2019, we have recorded related royalties of $0.2 million. During the year ended December 31, 2018, we have recorded related royalties of $0.1 million. 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.

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.

If AMF terminates the License Agreement under certain circumstances, we may be required to pay damages to AMF and AMF may have the right to terminate the license. In addition, if any of the royalties or other cash payments become due under the terms of the License Agreement, we may not have sufficient funds available to meet our payment obligations, which would allow AMF to terminate the License Agreement. Any termination or loss of rights (including exclusivity) under the License Agreement would materially and adversely affect our ability to develop and commercialize our r-SNM System, which in turn would have a material adverse effect on our business, operating results and prospects.

The License Agreement was amended twice in February 2014 in order to, among other things, include the field of the treatment of bladder and bowel 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 License Agreement allows AMF the right to use the AMF IP for non-commercial research, educational and scholarly purposes.

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 other approved SNM therapy offered by Medtronic, InterStim II and its predecessor, InterStim I. As our r-SNM System is 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;
- 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 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 major U.S. insurers, including Medicare. We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. We are initially targeting the estimated top 1,000 physicians 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. 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.

Our long-term growth depends, in part, on our ability to 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 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 introducing a second generation INS that extends the time between recharging sessions from once every one to two weeks to once a month, incorporating a modified header that allows us to connect our INS to an already implanted InterStim II lead, and over time, expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary-cell battery.

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 will depend on several factors 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 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 or product modifications 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;
- address competitive counter moves advanced by Medtronic to secure and maintain customers;
- develop an effective and dedicated sales and marketing team to provide adequate education and training to potential users of 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 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 September 30, 2019, we had 265 employees. We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the 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 and 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 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 bladder or bowel dysfunction 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 bladder and bowel dysfunction in the United States, Europe and worldwide is increasing. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for 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 bladder or bowel dysfunction 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 bladder or bowel dysfunction 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.

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, or the Term Loan. In October 2018, we and Silicon Valley Bank entered into an amendment to the Loan and Security Agreement, or the Loan Agreement, as so amended. 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 but no principal amortization 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.

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. Our limited historical experience in foreign markets may not provide us with enough data to accurately predict increased future demand in the United States. 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 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 have sales and operations both inside and outside the United States, including a limited sales and marketing organization outside the United States. Our international sales strategy is to increase our presence in Europe, Canada, and Australia, which 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. 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 results 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 have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. Our policies and procedures may not be sufficient to ensure that our directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, or that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, 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. We urge the purchasers of our securities to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing 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, premarket clearance and approval, record keeping procedures, advertising and promotion, recalls and field safety corrective actions, postmarket surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury, postmarket 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.

We are also 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. The manufacturers that we work with are similarly subject to periodic scheduled or unscheduled inspections of their facilities. Adverse findings during such inspections may impact our inventory and cause disruptions in product sales.

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

As an active-implantable device, our r-SNM System and our future product candidates are subject to the most stringent degree of medical device regulation. The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of medical device products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, with regulations differing from country to country. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based in part on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

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 or modification may not be approved or cleared by the FDA. Any modifications to 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 or generate additional data to submit to the FDA, future product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that the device is safe or effective for its intended uses;

- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of clinical studies or the interpretation of data from pre-clinical studies or clinical studies;
- serious and unexpected adverse device effects experienced by participants in clinical studies;
- the data from pre-clinical studies and clinical studies may be insufficient to support clearance or approval, where required;
- inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering clinical data or regulatory filings insufficient for clearance or approval.

The FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may impact our ability to modify our r-SNM System or introduce future products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain approvals once obtained. 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 postmarket 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 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. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or other similar regulatory authorities as reflected in the product's approved labeling. Physicians could use our r-SNM System on their patients in a manner that is inconsistent with the approved label. 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.

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 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 expand the indications for 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.

In order to obtain PMA approval for a device or expanded indications, the sponsor must meet the regulatory submission requirements of the FDA, which in many cases may require a PMA applicant to conduct well-controlled clinical studies designed to assess the safety and effectiveness of the product. Conducting clinical studies is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical studies but cannot be certain that the trials will ever result in commercial revenue. We may experience significant setbacks in clinical studies, even after earlier clinical studies showed promising results, and failure can occur at any time during the clinical study process. A device could malfunction or produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical studies. We, the FDA, or another regulatory authority may suspend or terminate clinical studies at any time to avoid exposing trial participants to unacceptable health risks.

Successful results of pre-clinical studies are not necessarily indicative of future clinical study results, and predecessor clinical study results may not be replicated in subsequent clinical studies. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical studies, or may find the clinical study design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical studies.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include obtaining the right to affix the CE mark to certain products in the EU, submitting an IDE to the FDA, applying to commence a pivotal clinical study for a new product, enrolling patients in clinical studies, releasing data from clinical studies, and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates and public announcements, in some cases for reasons beyond our control.

Clinical studies are necessary to support PMA applications and may be necessary to support PMA supplements for modified versions of our 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 may need to conduct additional clinical studies in the future 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 the device. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial, or result in the failure of the clinical trial.

Clinical studies must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with supplies of our product produced under cGMP requirements and other regulations. Furthermore, we rely on clinical study sites to ensure the proper and timely conduct of our clinical studies and we have limited influence over their performance. We depend on our collaborators and on medical institutions and employees to conduct our clinical studies in compliance with good clinical practice, 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 any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, the limit our ability to commercialize the product. 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.

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.

We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, registration, and listing of our r-SNM System. For example, we are required to submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. We have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our 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 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 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 is 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 or result in it being adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with the manufacturing processes for our 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, 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 treatment guidelines for OAB, FI or UR change or the standard of care evolves, we may need to redesign and seek a new marketing authorization from the FDA for our r-SNM System.

If treatment guidelines for OAB, FI or UR 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.

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.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that our 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, 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 the United States, 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, or make it more difficult to obtain approval for additional indications 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.

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

Litigation or other proceedings or third-party claims of intellectual property infringement against us, including the Medtronic Litigation, or any of our current or future licensors, including AMF, could require us to spend significant time and money and could prevent us from selling our 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. Because we have not conducted a formal freedom to operate analysis for patents related to our products, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our products. Even in the event that we conduct a formal freedom to operate analysis, patent searches to determine whether our products infringe patents held by third parties are inherently uncertain and such searches cannot assure

that all relevant patents are identified. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications for other patents now pending or recently revived patents of which we are unaware that our 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. For example, on November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc., which we collectively refer to as the Medtronic Affiliates, filed an initial complaint against us in the United States District Court for the Central District of California, Case No. 8:19-cv-2115. We refer to this matter as the Medtronic Litigation. The complaint asserts that our r-SNM System infringes U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324 and 9,821,112, or the Medtronic Patents, each of which is held by the Medtronic Affiliates, or the Medtronic Patents. The complaint requests customary remedies for patent infringement, including (i) a judgment that we have infringed and are infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) attorneys' fees, (iv) a permanent injunction preventing us from infringing the Medtronic Patents, (v) costs, and expenses and interest and (vi) any relief as the court deems just and appropriate. Given the early stage of the Medtronic Litigation, we are unable to predict the likelihood of success of the claims of the Medtronic Affiliates against us or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and is likely to require us to dedicate significant financial resources and management time and resources to our defense. An adverse ruling against us could materially and adversely affect our business, financial position, results of operations or cash flows and could also result in reputational harm. Specifically, an adverse ruling could, among other things, require us to pay substantial monetary damages to the Medtronic Affiliates for our activities that are found to infringe the Medtronic Patents and result in an injunction being granted limiting our ability to sell our r-SNM system. Similarly, in the event both parties agree to settle the Medtronic Litigation outside of court, such a settlement may require us to pay royalties or other payments, which could be substantial, or limit our ability to sell our r-SNM system . Even if we are successful in defending against these claims, the Medtronic Litigation could result in delays in future product developments, reputational harm or other collateral consequences. 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. If any third-party intellectual property were held by a court of competent jurisdiction to cover our r-SNM System, including in connection with the Medtronic Litigation, the holders of any such intellectual property may be able to block our ability to commercialize our product unless we obtain a license under the applicable intellectual property, or until such intellectual property expires. Similarly, if any third-party intellectual property were held by a court of competent jurisdiction to cover aspects of our methods of use, the holders of any such intellectual property may be able to block our ability to develop and commercialize the applicable product unless we obtain a license or until such intellectual property expires. In either case, such a license may not be available on commercially reasonable terms or at all and we may be required to pay damages, which could be substantial, in connection with our activities prior to obtaining such a license.

Defense of any of the above claims, including the Medtronic Litigation, would require us to dedicate substantial time and resources, which time and resources could otherwise be used by us toward the maintenance of our own intellectual property and the commercialization of our 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 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 September 3, 2019, we wholly owned 23 issued U.S. patents and 56 issued foreign patents, and 19 pending U.S. patent applications and 53 pending foreign patent applications. We also license from AMF 27 issued U.S. patents and four pending U.S. patent applications, as well as 58 issued foreign patents and 14 pending foreign patent applications. Issued patents owned or used by us will expire between 2021 and 2039.

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 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 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.

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, or 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, or 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 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 for additional indications or for 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 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;
- the results of any future legal proceedings; and
- other factors described in this "Risk Factors" section.

In addition, in the past, stockholders have initiated class action lawsuits against companies following periods of volatility in the market prices of these companies' common stock. Such litigation, if instituted against us, regardless of the merit or ultimate results of such litigation, could cause us to incur substantial costs and divert management's attention and resources.

We are 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 of 2002, as amended, or 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.

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 Securities Exchange Act of 1934, or the Exchange Act, as well as the listing requirements, or the Nasdaq Marketplace Rules, of 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 are in the process of undertaking 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, our internal control over financial reporting is perceived as inadequate or we are unable to produce timely or accurate financial statements, investors may lose confidence in 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 JOBS Act, depending on whether we continue 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, or 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. However, in light of the decision issued by the Court of Chancery in Sciabacucchi v. Salzberg, C.A. No. 2017-0931-JTL, invalidating similar provisions in the certificates of incorporation of three other Delaware corporations, we do not currently intend to enforce the foregoing federal forum selection provision unless the *Sciabacucchi* decision is appealed and the Delaware Supreme Court reverses the Chancery Court's decision. If the decision is not appealed or if the Delaware Supreme Court affirms the Chancery Court's decision, then we will seek approval by our stockholders to amend our certificate of incorporation at our next regularly scheduled annual meeting of stockholders to remove the federal forum selection provision.

Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to these provisions of our certificate of incorporation. These choice of forum provisions may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will rely in part on the research and reports that securities or industry analysts publish about us and our business. If one or more of the analysts who cover us downgrades our common stock or issues other unfavorable commentary or research the price of our common stock may decline. If one or more analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline and could result in the loss of all or part of your investment in us.

Risks Related to this Offering

Because the public offering price of our common stock will be substantially higher than the as adjusted net tangible book value per share of our outstanding common stock before giving effect to this offering, new investors will experience immediate and substantial dilution.

The public offering price per share of common stock will be substantially higher than the as adjusted net tangible book value per share of our common stock before giving effect to this offering based on the total value of our tangible assets less our total liabilities. Therefore, if you purchase shares of our common stock in this offering, you

will experience immediate dilution of $ per share, based on the public offering price of $ per share, and our as adjusted net tangible book value per share as of September 30, 2019 after giving effect to this offering. To the extent outstanding stock options or warrants to purchase shares of our common stock are exercised, or any restricted stock units are settled, new investors may incur further dilution. See the section titled "Dilution" for more information.

Our management will have broad discretion over the actual amounts and timing of the expenditure of the proceeds of this offering and might not apply the proceeds in ways that enhance our operating results or increase the value of your investment.

We intend to allocate the net proceeds from this offering (i) to support the commercial launch of our r-SNM System in the United States, Europe and Canada, (ii) to conduct SNM-related research and development activities and to fund the technological enhancement of our r-SNM System and (iii) for working capital and general corporate purposes. Our management will have broad discretion over the actual amounts and timing of the expenditure of the net proceeds from this offering within those categories, and accordingly, investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds, with only limited information concerning management's specific intentions. Our management might not apply the proceeds in ways that enhance our operating results or increase the value of your investment. We may pursue commercialization strategies, clinical studies, regulatory approvals or collaborations that do not result in an increase in the market value of our common stock and that may increase our losses. Our failure to allocate and spend the net proceeds from this offering effectively could harm our business, financial condition and results of operations. Pending our use of the net proceeds from this offering, we may invest the net proceeds in a variety of capital preservation investments, including short and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

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 the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of common stock, based on 28,602,766 shares outstanding as of November 13, 2019. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, shares held by our directors, executive officers and the selling stockholders are subject to a contractual lock-up with the underwriters for this offering for a lock-up period of 60 days from the date of this prospectus supplement. These shares can be sold, subject to any applicable volume limitations under federal securities laws, after the earlier of the expiration of, or release from, the lock-up period. BofA Securities and Barclays may, in their discretion, release the restrictions on any such shares at any time without notice.

In addition, sales of shares of our common stock held by our directors, executive officers and the selling stockholders are permitted during the 60-day lock-up period if made pursuant to a trading plan established to satisfy Rule 10b5-1 of the Exchange Act if such plan was in effect as of the date of the applicable lock-up agreement. Such sales may also take place after the expiration of the 60-day lock-up period if made pursuant to any trading plan established to satisfy Rule 10b5-1 of the Exchange Act, regardless of when the plan was established.

Moreover, even after this offering, holders of a majority of our common stock will have rights, subject to some 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. We have also registered or plan to register all shares of common stock that we may issue under our equity plans. As a result, these shares, when registered, will be able to be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above, to the extent applicable.

Cautionary Note Regarding Forward-Looking Statements

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of 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, in the accompanying prospectus or the documents incorporated by reference herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, or other comparable terms intended to identify statements about the future. Forward-looking statements include, but are not limited to, statements about:

- our ability to maintain regulatory approvals of our r-SNM System;
- our ability to successfully commercialize our r-SNM System in the United States and internationally;
- commercial success, ability to capture market share and market acceptance of our r-SNM System;
- our ability to enhance our r-SNM System;
- our ability to achieve and maintain adequate levels of coverage or reimbursement for our r-SNM System;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize our r-SNM System;
- our ability to accurately forecast customer demand for our r-SNM System and manage our inventory;
- our ability to retain our senior management and hire other highly qualified personnel, including a sales force;
- developments and projections relating to our competitors and our industry, including competing products and therapies for the treatment of OAB, FI and UR;
- the accuracy of our estimates regarding expenses, future revenue and needs for additional financing;
- FDA or other United States or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States and international markets;
- the timing or likelihood of regulatory filings and approvals or clearances;
- any supplier shortages related to our r-SNM System or its components and any manufacturing disruptions which may impact our inventory supply as we expand our business;
- our ability to establish and maintain intellectual property protection for our r-SNM System or avoid or defend claims of infringement of third party intellectual property, including from the Medtronic Litigation;
- the volatility of the trading price of our common stock; and
- our use of the net proceeds from this offering.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions described under the section entitled “Risk Factors” and elsewhere in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein. We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances described in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements may never be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus supplement to conform these statements to actual results or to changes in our expectations.

You should read this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein 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.

Statistical Data

We obtained the industry, statistical and market data in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. All of the market data used in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein involves a number of assumptions and limitations. While we believe that the information from these industry publications, surveys and studies is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ million from the sale of the shares of common stock offered by us in this offering (or approximately $ million if the underwriters exercise their option to purchase additional shares in full), based on the public offering price of $ per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders.

We intend to use the net proceeds from this offering (i) to support the commercial launch of our r-SNM System in the United States, Europe and Canada, (ii) to conduct SNM-related research and development activities and to fund the technological enhancement of our r-SNM System and (iii) for working capital and general corporate purposes.

As of the date of this prospectus supplement, we cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments or other securities.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the assumed public offering price per share and the as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value is the amount of our total tangible assets less our liabilities. Our historical net tangible book value per share is our historical net tangible book value divided by the number of shares of common stock outstanding as of September 30, 2019. Our historical net tangible book value as of September 30, 2019 was approximately $91.8 million, or $3.21 per share of common stock.

After giving further effect to our sale of shares of our common stock in this offering at the public offering price of $ per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2019 would have been approximately $ million, or approximately $ per share. This amount represents an immediate increase (decrease) in as adjusted net tangible book value of $ per share to our existing stockholders and immediate dilution in as adjusted net tangible book value of approximately $ per share to new investors purchasing shares of our common stock in this offering. We determine dilution by subtracting our as adjusted net tangible book value per share after this offering from the amount of cash per common share paid by new investors in this offering.

The following table illustrates per share dilution:

Assumed public offering price per share		$
Historical net tangible book value per share as of September 30, 2019	$ 3.21	
Increase (Decrease) in net tangible book value		
As adjusted net tangible book value per share after this offering		
Dilution in net tangible book value per share to investors purchasing in this offering		$

The information above assumes that the underwriters do not exercise their option to purchase additional shares. If the underwriters exercise in full their option to purchase an additional shares of our common stock at the public offering price, as adjusted net tangible book value per share after this offering will increase to $, representing an immediate increase (decrease) in as adjusted net tangible book value per share to our existing stockholders of $ per share and immediate dilution in as adjusted net tangible book value of $ per share to new investors purchasing shares of our common stock in this offering.

The foregoing discussion and table is based on 28,633,911 shares of our common stock outstanding as of September 30, 2019, and excludes as of that date:

- 1,146,738 shares of our common stock issuable upon the exercise of outstanding stock options under our 2014 Stock Incentive Plan, as amended, or the 2014 Plan, at a weighted-average exercise price of $1.40 per share, and 1,485,028 shares of our common stock issuable upon the exercise of outstanding stock options under our 2018 Omnibus Incentive Plan, or the 2018 Plan, at a weighted-average exercise price of $20.15 per share;
- 92,672 shares of our common stock issuable upon the vesting and settlement of restricted stock units outstanding under the 2018 Plan; and
- 2,447,071 shares of our common stock reserved for future issuance under the 2018 Plan.

To the extent any of the outstanding stock options described above are exercised, any outstanding restricted stock units described above are settled, or new options or restricted stock units are issued, there will be further dilution to

investors participating in this offering. Furthermore, we may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors purchasing in this offering.

SELLING STOCKHOLDERS

The following table sets forth the name of the selling stockholders, the number of shares of common stock owned by the selling stockholders immediately prior to the date of this prospectus supplement and the number of shares of common stock to be offered by the selling stockholders pursuant to this prospectus supplement. The table also provides information regarding the beneficial ownership of shares of our common stock by the selling stockholders as adjusted to reflect the assumed sale of all of the shares offered by us under this prospectus supplement (assuming no exercise by the underwriters of their option to purchase additional shares of our common stock from us). Beneficial ownership is based on information furnished by the selling stockholders. Unless otherwise indicated, each of the selling stockholders named in the following table, to our knowledge, has sole voting and investment power with respect to the shares beneficially owned by it.

Pursuant to the rules and regulations of the SEC, beneficial ownership includes any shares of common stock as to which a selling stockholder has sole or shared voting power or investment power and any shares of common stock that the selling stockholder has the right to acquire within 60 days of November 13, 2019. The percent of beneficial ownership for each selling stockholder is based on 28,602,766 shares of our common stock outstanding as of November 13, 2019.

The selling stockholders have contractual rights to require us to file the registration statement of which this prospectus supplement is a part, as described under "Description of Capital Stock—Registration Rights" elsewhere in the accompanying prospectus.

	Shares of Common Stock Beneficially Owned Prior to Offering		Number of Shares of Common Stock Being Offered	Shares of Common Stock Beneficially Owned Upon Completion of this Offering	
Name of Selling Stockholder	**Number**	**Percentage**		**Number**	**Percentage**
BioDiscovery 4 FCPR[(1)]	2,690,795	9.4%			
Raymond W. Cohen[(2)]	860,151	3.0%			
Dan L. Dearen[(3)]	453,473	1.6%			

(1) Andera Partners is the manager of BioDiscovery 4 FCPR and has voting and dispositive power over the shares held by BioDiscovery 4 FCPR. Raphaël Wisniewski, who is a member of our board of directors, is a partner of Andera Partners, and may be deemed to have voting and dispositive power over the shares held by BioDiscovery 4 FCPR. Mr. Wisniewski disclaims beneficial ownership of such shares. The mailing address of BioDiscovery 4 FCPR is 347 Rue Saint St Honoré, 75001 Paris Cedex 08 France.

(2) Consists of (i) 683,391 shares of common stock held by Mr. Cohen, (ii) 168,000 shares of common stock underlying stock options exercisable within 60 days of November 13, 2019, and (iii) 8,760 shares of common stock held by the Cielo Trust established March 30, 2018. Mr. Cohen is a trustee of the Cielo Trust established March 30, 2018, and as a result, shares voting and dispositive power over the shares held by it.

(3) Consists of (i) 138,491 shares of common stock held by Mr. Dearen, and (ii) 314,982 shares of common stock underlying stock options exercisable within 60 days of November 13, 2019.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion describes the material U.S. federal income tax considerations for Non-U.S. Holders (as defined below) with respect to the acquisition, ownership and disposition of our common stock acquired in this offering. This discussion does not address all aspects of U.S. federal income tax law that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address any U.S. federal estate or gift tax, or any state, local or non-U.S. tax consequences or U.S. federal tax consequences other than income taxes. Non-U.S. Holders should consult their tax advisors as to these matters. Rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code such as:

- banks, financial institutions, or insurance companies;
- tax-exempt organizations;
- tax-qualified retirement plans;
- broker-dealers and traders in securities, commodities or currencies;
- certain former citizens or long-term residents of the United States;
- persons that own, or are deemed to own, more than five percent of our common stock (except to the extent specifically set forth below);
- regulated investment companies or real estate investment trusts;
- “controlled foreign corporations,” “passive foreign investment companies,” or corporations that accumulate earnings to avoid U.S. federal income tax;
- persons that hold our common stock as part of a “straddle,” “hedge,” “conversion transaction,” “synthetic security” or other integrated investment or risk reduction strategy;
- holders deemed to sell our common stock under the constructive sale provisions of the Code;
- holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation;
- holders who are subject to the alternative minimum tax or Medicare contribution tax; or
- partnerships and other pass-through entities or arrangements, and investors in such pass-through entities or entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their places of organization or formation).

Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and Treasury regulations, published administrative pronouncements, rulings and judicial decisions thereunder as of the date hereof. Such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary. In addition, the IRS could challenge one or more of the tax consequences described herein.

This discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice for any Non-U.S. Holders under their particular circumstances. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction or under any applicable tax treaty, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences.

For the purposes of this discussion, a "Non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of our common stock that is not a U.S. Holder. A "U.S. Holder" means a beneficial owner of our common stock that is, for U.S. federal income tax purposes, (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a United States person. Also, partnerships, or other entities or arrangements that are treated as partnerships for U.S. federal income tax purposes (regardless of their place of organization or formation) and entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their place of organization or formation), are not addressed by this discussion and are, therefore, not considered to be Non-U.S. Holders for the purposes of this discussion. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

Distributions on Our Common Stock

We do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, distributions of cash or property, if any, made on our common stock to a Non-U.S. Holder of our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide us with a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. In the case of a Non-U.S. Holder that is an entity, Treasury regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you should consult with your tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain

circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce your adjusted basis in our common stock as a non-taxable return of capital, but not below zero, and then any excess will be treated as gain and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a United States real property holding corporation, or a USRPHC, within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period for the relevant shares of our common stock. In the case of gain described in (a) above, a Non-U.S. Holder generally will be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies, and a corporate Non-U.S. Holder may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. An individual Non-U.S. Holder described in (b) above generally will be subject to U.S. federal income tax at a rate of 30% on the gain derived from the sale (or such lower rate as may be specified by an applicable income tax treaty), which gain may be offset by certain of the Non-U.S. Holder's U.S. source capital losses (even though the Non-U.S. Holder is not considered a resident of the United States), provided the Non-U.S. Holder timely files U.S. federal income tax returns with respect to such losses. With respect to (c) above, in general, we would be a USRPHC if our interests in U.S. real property interests constituted (by fair market value) at least half of our assets. We believe that we are not, and do not anticipate becoming, a USRPHC; however, there can be no assurance that we will not become a USRPHC in the future. Even if we are treated as a USRPHC, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (a) the five-year period preceding the disposition or (b) the holder's holding period for the relevant shares of our common stock and (2) our common stock is "regularly traded," as defined by applicable Treasury regulations, on an established securities market. There can be no assurance that our common stock will qualify as regularly traded on an established securities market.

Information Reporting Requirements and Backup Withholding

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock, including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder that provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, or other appropriate form, or otherwise establishes an exemption.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or non-U.S., unless the holder provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, IRS Form W-8ECI or other appropriate form, or otherwise establishes an exemption. Generally, U.S.

information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. Non-U.S. Holders you should consult with their tax advisors to determine if they are eligible to obtain a tax refund or credit with respect to amounts withheld under the backup withholding rules.

Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such sections are commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a U.S. federal withholding tax of 30% may apply to dividends on our common stock paid to a foreign financial institution (as specifically defined by applicable rules), including when the foreign financial institution holds our common stock on behalf of a Non-U.S. Holder, unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which may include certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing these withholding and reporting requirements may be subject to different rules. FATCA withholding tax will also apply to dividends on our common stock paid to a non-financial foreign entity (as specifically defined by applicable rules) unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. Withholding under FATCA will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules.

Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. Holders are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

UNDERWRITING

BofA Securities, Inc. and Barclays Capital Inc. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us, the selling stockholders and the underwriters, we and the selling stockholders have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us and the selling stockholders, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
Barclays Capital Inc.	
Wells Fargo Securities, LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We and the selling stockholders have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us and the selling stockholders that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus supplement and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed. No such change will change the amount of proceeds to be received by us or the selling stockholders as set forth on the cover page of this prospectus supplement.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us and the selling stockholders. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares from us and the selling stockholders.

	Per Share	Without Option	With Option
Public offering price			
Underwriting discount paid by us			
Underwriting discount paid by the selling stockholders			
Proceeds, before expenses, to us			
Proceeds, before expenses, to the selling stockholders			

The expenses of the offering, not including the underwriting discount, are estimated at $ and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to $10,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus supplement, to purchase up to an additional $16,500,000 of shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our directors, executive officers, and the selling stockholders, have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 60 days after the date of this prospectus supplement without first obtaining the written consent of BofA Securities, Inc. and Barclays Capital Inc. Specifically, we and these other persons have agreed, subject to certain exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file a registration statement or make a confidential submission related to the common stock,
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise, or
- publicly disclose the intention to do any of the foregoing.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

BofA Securities, Inc. and Barclays Capital Inc., in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice. In addition, in the event that any stockholder holding in excess of 5% of our outstanding shares of capital stock, or a Major Holder, is granted an early release from the lock-up restrictions with respect to our securities in an aggregate amount in excess of 1% of our issued and outstanding shares of capital stock (whether in one or multiple releases), then each other Major Holder automatically will be granted an equivalent early release from its obligations under the lock-up agreement on a pro rata basis. Such release shall not be applicable in the event of an underwritten primary or secondary public offering or sale of our common stock during the period ending 60 days after the date of this prospectus supplement. Notwithstanding any other provisions of the lock-up agreement, if BofA Securities, Inc. and Barclays Capital Inc., in their reasonable judgment, after consultation with us, determine that a stockholder

should be granted an early release from the lock-up agreement due to circumstances of an emergency or hardship, then no other Major Holder shall have any right to be granted an early release from the lock-up agreement.

Nasdaq Global Select Market Listing

Our common stock trades on the Nasdaq Global Select Market under the trading symbol "AXNX." On November 18, 2019, the last reported sale price of our common stock on Nasdaq was $23.43 per share.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area, each of which is referred to herein as a Member State, no shares have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of our representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed with us that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant Member State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, our representatives and our respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgments and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

The above selling restriction is in addition to any other selling restrictions set out below.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order, all such persons together being referred to as "relevant persons". This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus supplement relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus supplement is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for the prospectus supplement. The shares to which this prospectus supplement relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus supplement you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus

does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus supplement contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus supplement is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus supplement has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus supplement or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated

or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law; or
- as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the securities being offered by this prospectus supplement will be passed upon for us by K&L Gates LLP, Irvine, California. Certain legal matters with respect to this offering will be passed upon for the underwriters by Shearman & Sterling LLP.

EXPERTS

The consolidated financial statements as of and for the years ended December 31, 2018 and 2017 incorporated by reference in this prospectus supplement have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-3, including exhibits and schedules, under the Securities Act of 1933, as amended, with respect to the shares of common stock offered hereby. This prospectus supplement and the accompanying prospectus, which constitute a part of the registration statement, do not contain all of the information set forth in the registration statement and its exhibits. For further information with respect to us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus supplement and the accompanying prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. You should review the complete document to evaluate these statements. You may obtain copies of the registration statement and its exhibits via the SEC's EDGAR database.

We file annual, quarterly and current reports, proxy statements and other documents with the SEC under the Exchange Act. The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers, including our company, that file electronically with the SEC. You may obtain documents that we file with the SEC at http://www.sec.gov.

We also make these documents available on our website at www.axonicsmodulation.com. Our website and the information contained or connected to our website is not incorporated by reference in this this prospectus supplement and the accompanying prospectus, and you should not consider it part of this this prospectus supplement and the accompanying prospectus. You may also request a copy of these filings, at no cost, by writing us at 26 Technology Drive, Irvine, CA 92618, Attention: General Counsel or telephoning us at (949) 396-6322.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus supplement certain of the information we file with the SEC. This means we can disclose important information to you by referring you to another document that has been filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus supplement, and information that we file later with the SEC will automatically update and supersede information contained in this prospectus supplement and the accompanying prospectus. We incorporate by reference the documents listed below that we have previously filed with the SEC:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 5, 2019, as amended by our Annual Report on Form 10-K/A for the year ended December 31, 2018, as filed with the SEC on April 30, 2019;
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 from our Definitive Proxy Statement on Schedule 14A (other than information furnished rather than filed) filed with the SEC on July 9, 2019;

- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2019 as filed with the SEC on May 8, 2019; for the quarter ended June 30, 2019, as filed with the SEC on August 5, 2019; and for the quarter ended September 30, 2019, as filed with the SEC on November 14, 2019;

- our Current Reports on Form 8-K (other than information furnished rather than filed) filed with the SEC on March 5, 2019 (excluding item 2.02), April 12, 2019, June 11, 2019, July 12, 2019, August 22, 2019, September 9, 2019, November 6, 2019 and November 14, 2019 (excluding item 2.02); and

- the description of our common stock contained in our Registration Statement on Form 8-A filed with SEC on October 25, 2018, including any amendment or report filed for the purpose of updating such description.

We also incorporate by reference into this prospectus supplement additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the completion or termination of the offering of the securities described in this prospectus supplement, excluding any information deemed furnished and not filed with the SEC. Any statements contained in a previously filed document incorporated by reference into this prospectus supplement are deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

We will furnish without charge to each person, including any beneficial owner, to whom this prospectus supplement is delivered, on written or oral request, a copy of any or all of the documents incorporated by reference into this prospectus supplement, including exhibits to these documents. You should direct any requests for documents to Axonics Modulation Technologies, Inc., 26 Technology Drive, Irvine, CA 92618, Attention: General Counsel or telephoning us at (949) 396-6322. You may also access the documents incorporated by reference into this prospectus supplement through our website at www.axonicsmodulation.com. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated into this prospectus supplement, the accompanying prospectus or the registration statement of which it forms a part.

PROSPECTUS

$200,000,000
Common Stock
Preferred Stock
Debt Securities
Warrants
Units
Rights

9,061,028 Shares
Common Stock
Offered by the Selling Stockholders

From time to time, we may offer and sell up to an aggregate amount of $200,000,000 of any combination of the securities described in this prospectus, either individually or in combination, in one or more offerings. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants or rights.

The selling stockholders named herein may offer and sell from time to time up to an aggregate of 9,061,028 shares of common stock, in one or more offerings. All of these shares of common stock are outstanding shares of common stock held by the selling stockholders. We will not receive any proceeds from sales of common stock by the selling stockholders.

Our common stock is listed on the Nasdaq Global Select Market, or Nasdaq, under the trading symbol "AXNX." On November 5, 2019, the last reported sale price of our common stock on Nasdaq was $23.38 per share.

We are an "emerging growth company" under the federal securities laws and, as such, are subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in our securities involves a high degree of risk. Please read "Risk Factors" on page 4 of this prospectus and in any applicable prospectus supplement and in the documents incorporated by reference herein and therein for a discussion of the factors you should carefully consider before deciding to invest in our securities.

We will provide the specific terms of any securities we may offer in supplements to this prospectus. You should read this prospectus and any accompanying prospectus supplement carefully before you invest. This prospectus may not be used to offer and sell any securities unless accompanied by a prospectus supplement describing the amount of and terms of the offering of those securities.

We may offer and sell the securities described in this prospectus to or through one or more underwriters, dealers or agents, or directly to purchasers on an immediate, continuous or delayed basis. The names of any underwriters, dealers or agents involved in the sale of any securities, the specific manner in which they may be offered and any applicable commissions or discounts will be set forth in an accompanying prospectus supplement covering the sales of those securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 18, 2019

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You should rely only on the information contained in or incorporated by reference into this prospectus, in any accompanying prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. Neither we nor the selling stockholders have authorized any person to give any information or to make any representations other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement, or any free writing prospectuses prepared by or on behalf of us or to which we have referred you, and, if given or made, you must not rely upon the information or representations as having been authorized. This prospectus, any accompanying prospectus supplement and any free writing prospectuses prepared by or on behalf of us or to which we have referred you, do not constitute an offer to sell or the solicitation of an offer to buy securities, nor do this prospectus or any accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation. The information contained in this prospectus, any accompanying prospectus supplement, and any free writing prospectuses prepared by or on behalf of us or to which we have referred you, speaks only as of the date set forth on the cover page and may not reflect subsequent changes in our business, financial condition, results of operations and prospects even though this prospectus, any accompanying prospectus supplement, and any free writing prospectuses prepared by or on behalf of us or to which we have referred you, is delivered or securities are sold on a later date.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, utilizing a "shelf" registration process. Under this shelf registration statement, we may from time to time sell any one or more, or a combination of, the securities described in this prospectus in one or more offerings for up to a total dollar amount of $200,000,000. In addition, the selling stockholders may, from time to time, sell up to an aggregate of 9,061,028 shares of common stock from time to time in one or more offerings as described in this prospectus. This prospectus provides you with a general description of the securities we may offer. Each time we offer and sell our securities, we will provide one or more prospectus supplements that will contain specific information about the terms of the offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings.

This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. Each prospectus supplement and any free writing prospectuses prepared by or on behalf of us or to which we have referred you may also add, update or change information contained in this prospectus and may include a discussion of any risk factors or other special considerations that apply to the offered securities.

Before making an investment decision, it is important for you to read and consider the information contained in this prospectus, any accompanying prospectus supplement, and any free writing prospectuses prepared by or on behalf of us or to which we have referred you, together with the additional information described under the heading "Where You Can Find More Information" and "Incorporation of Certain Information by Reference" below.

This prospectus may not be used to offer to sell, solicit an offer to buy or consummate a sale of securities unless it is accompanied by a prospectus supplement. If there is any inconsistency between information in this prospectus and any accompanying prospectus supplement, you should rely on the information in the latest supplement and documents incorporated by reference herein and therein.

This prospectus 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 prospectus also includes trademarks and trade names that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this prospectus 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.

Unless otherwise indicated herein, references in this prospectus to "Axonics," "our company," "we," "us" and "our" refer to Axonics Modulation Technologies, Inc. and our consolidated subsidiaries.

ABOUT THE COMPANY

Overview

We are a medical technology company that has developed and is commercializing an innovative and minimally invasive implantable neurostimulation system for sacral neuromodulation, or SNM, therapy. SNM therapy is primarily used to treat patients with urinary urge incontinence, or UUI, and urinary urgency frequency, or UUF, together referred to as overactive bladder, or OAB, fecal incontinence, or FI, and non-obstructive urinary retention, or UR. We believe our proprietary SNM system, or our r-SNM System, has the potential to disrupt and grow the approximately $650 million, as of 2018, global SNM market, which is currently served by Medtronic plc, or Medtronic, as a single participant.

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 bladder and bowel 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 is 60% smaller than the InterStim II System, or InterStim II, which is the only other approved SNM product and is marketed by Medtronic.

Our r-SNM System received premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, on September 6, 2019 for the treatment of FI, and we have also submitted a PMA application to the FDA for OAB and UR. We also have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR.

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

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

- The study has passed the six-month primary endpoint and completed one-year follow up;
- 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 one year, 115 of the 129 implanted patients, or 89%, continued to be therapy responders;
- At six months, 93% of all implanted patients reported being “satisfied” with the therapy, and at one year, 93% of all implanted patients continued to report being “satisfied” with the therapy;
- No serious device-related adverse events have been reported.
- We submitted the complete six-month results of the study to the FDA as an amendment to our previously submitted PMA, and intend to follow patients out to two years; and
- On October 24, 2019, we submitted one-year follow up data to the FDA as part of our annual investigational device exemption, or IDE, update process.

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

- The study has completed one-year follow-ups and two-year follow-ups;
- 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;
- At 12 months, 84% of test responders and 77% of all implanted patients were “very” or “moderately” satisfied with the therapy provided by our r-SNM System; and
- No serious device-related adverse events have been reported.

We believe that our r-SNM System offers similar therapeutic benefits and competitive advantages to the only currently available SNM technology, InterStim II, offered by Medtronic. We believe that our r-SNM System is the first and only system for SNM therapy with a rechargeable implantable neurostimulator, or 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. We also received CE Mark for our r-SNM System for 1.5T/3.0T MRI full-body conditional labeling on February 22, 2019 and FDA approval for our r-SNM System for 1.5T MRI full-body and 3.0T head conditional labeling on September 6, 2019. Our r-SNM

System allows full-body MRI scans and head scans under certain conditions, 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 a body part other than the head, which is currently required for patients implanted with InterStim II. This full-body MRI 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 to fabricate 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, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, 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 clinician programmer that guides the implanting physician through electrode placement and stimulation programming.

Recent Developments

On November 4, 2019, certain affiliates of Medtronic filed a lawsuit against us in the United States District Court for the Central District of California. The lawsuit asserts that our r-SNM System infringes certain patents owned by these affiliates of Medtronic and seeks customary remedies for patent infringement. We intend to vigorously defend against these claims.

Implications of Being an Emerging Growth Company

We qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public 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 of 2002, as amended, or 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.

In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected not to take advantage of this transition period. We will remain an emerging growth company until the earliest of (i) December 31, 2023, (ii) the first fiscal year after our annual gross revenues exceed $1.07 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year.

Corporate 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. 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 prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our securities.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the following information about these risks, as well as the information set forth under the heading "Risk Factors" in our 2018 Annual Report, together with the other information appearing elsewhere in this prospectus or any prospectus supplement or incorporated by reference in this prospectus or any prospectus supplement, including our consolidated financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in each of our 2018 Annual Report and 2019 Quarterly Reports, before deciding to invest in our securities. The occurrence of any of these risks could have a material and adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Business and Strategy

We currently depend on the commercialization of our r-SNM System, which is our only product and is only approved in the United States for the treatment of FI. Our r-SNM System may not receive FDA regulatory approval for additional indications, or we may be significantly delayed in receiving FDA regulatory approval for additional indications. Even if we receive FDA regulatory approval for additional indications, we may not be able to successfully commercialize our r-SNM System.

We currently have only one product, our r-SNM System, which is only approved in the United States for the treatment of FI. Our business depends significantly on our ability to obtain regulatory approval from the FDA for our r-SNM System for OAB and UR, 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 other marketable products or enhancements to our r-SNM System. We are not permitted to market our r-SNM System in the United States for the treatment of OAB and UR until we receive approval from the FDA for those indications. 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. We cannot assure you that approval by the FDA of our r-SNM System for the treatment of FI means that the FDA will also approve our r-SNM System for the treatment of OAB and UR.

Our near-term prospects, including our ability to finance our company and generate revenue, as well as our future growth, depend significantly on the successful and timely regulatory approval from the FDA for the treatment of OAB and UR 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 for the treatment of OAB and UR;
- 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;
- our 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 for the indications for which we have received FDA approval;
- our ability to successfully commercialize 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.

We could experience significant delays in obtaining marketing approval for OAB and UR from the FDA for our r-SNM System or not obtain approval for those indications at all. Even if we obtain FDA regulatory approval for OAB and UR, 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, and we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.

We are a medical technology company with a limited operating history. To date, we have invested substantially all of our efforts in the research and development of, seeking regulatory approval for, and commercialization of our 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.

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, for the years ended December 31, 2018 and 2017, we have recorded net losses of $32.5 million and $18.1 million, respectively, and for the six months ended June 30, 2019 and 2018, we have recorded net losses of $32.2 million and $15.3 million, respectively. As of June 30, 2019, we had an accumulated deficit of $131.8 million. To date, we have financed our operations through equity financings, including our initial public offering, and amounts borrowed under the Loan Agreement (as 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.

We expect that our operating expenses will continue to increase as we (i) continue to build our commercial infrastructure, (ii) develop, enhance, and begin to commercialize our r-SNM System in the United States, (iii) seek FDA regulatory approval for our r-SNM System in the United States for OAB and UR, (iv) increase our commercialization efforts internationally, and (v) incur additional operational costs associated with being a public company. For example, we hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States and expect to grow our sales force over time. If we are delayed in obtaining approval of our r-SNM System by the FDA for OAB and UR, 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. Further, if we do obtain approval of our r-SNM System from the FDA for OAB and UR, we will need to pay our U.S. sales team increased compensation in the form of product sales commissions, which will increase our operating expenses. 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.

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 OAB and UR without significant delay or restrictions;
- the effectiveness of our marketing and sales efforts in the United States and internationally;

- our success in educating physicians and patients about the benefits, administration and use of our r-SNM System;
- the acceptance by physicians and patients of the safety and effectiveness of our r-SNM System;
- our third-party manufacturers' and suppliers' ability to manufacture and supply the components of our r-SNM System in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements, and to remain in good standing with regulatory agencies;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing therapies;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to our 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 raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our r-SNM System;
- 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 began marketing and selling our r-SNM System in certain limited European markets in 2018 through a limited direct sales force that targets physicians and hospitals. In the United States, we began marketing and selling our r-SNM System in the fourth quarter of 2019 through our dedicated direct sales organization. As a result, we have limited experience marketing and selling our r-SNM System.

We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. However, we expect that our sales force will 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 our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent any of our sales force is comprised of personnel hired from our competitor, we may have to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. This may subject us to allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Addressing such allegations would be costly both in terms of time and resources. Any of these risks may adversely affect our business. Additionally, if we are delayed in obtaining approval of our r-SNM System by the FDA for OAB and UR, we may be required to offer increased compensation to our U.S. sales force in order to retain them. Notwithstanding, we may lose members of our U.S. sales force who do not want to, or are not able to, wait until we obtain approval from the FDA for other indications because they may be earning less than they would otherwise if our product were approved in the United States for other indications.

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, conducting clinical studies for our r-SNM System, and building our dedicated direct sales organization. We expect that certain of these activities and the associated expenses will continue. Our expenses have also increased substantially in connection with the commercialization of our r-SNM System in the United States, including hiring qualified personnel and retaining our sales team. Additional expenditures also include costs associated with manufacturing and supply, sales and marketing costs, costs and expenses incidental to being a public company, and general operations. In addition, other unanticipated costs may arise.

As of June 30, 2019, we had cash and cash equivalents of $82.7 million and short-term investments of $43.0 million.

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 OAB and UR and the associated costs;
- the costs associated with manufacturing, selling, and marketing our r-SNM System in the United States, including the cost and timing of implementing our sales and marketing plan and expanding our manufacturing capabilities;
- our ability to retain and compensate the highly qualified personnel necessary to execute our plans;
- our ability to effectively market and sell, and achieve sufficient market acceptance and market share for, our r-SNM System;
- the costs to maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;
- 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 postmarket 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 and reporting systems, incidental to being a public company.

We may need to raise additional capital, and if we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our 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 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 manufacturers 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, or 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 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.

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 depend on single source suppliers to manufacture certain of our components, sub-assemblies and materials, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition and results of operations.

We rely on single source suppliers in many instances for certain of the components, sub-assemblies and materials for our products. These components, sub-assemblies and materials are critical and there are relatively few alternative sources of supply. We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies and materials, and in some instances we do not carry a significant inventory of these items. While we believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that we would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses.

Our dependence on third-party suppliers subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier’s operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier’s failure to produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;

- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the laws and regulations enforced by the FDA and state regulatory authorities;
- inability to ensure the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the FDA's Quality Regulation System, or QSR, and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner.

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 us 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) bladder and bowel 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. We have the right to expand the field of use for the AMF Licensed Products to the 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.

The license is co-exclusive with AMF solely with respect to (i) AMF IP resulting from AMF's performance of any engineering services rendered under the License Agreement, and (ii) AMF's right to use AMF IP for non-commercial research, educational and scholarly purposes.

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, or 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. Any and all improvements to AMF IP made by us will be owned by AMF and licensed to us under the License Agreement. As of the date of this prospectus, 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, or 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 a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (i) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products and (b) a minimum annual royalty, or the Minimum Royalty, payable quarterly. The Minimum Royalty will automatically increase each year after 2018, subject to a maximum amount of $200,000 per year. As of June 30, 2019, we have accrued $0.1 million royalties toward the Minimum Royalty. As of December 31, 2018, we accrued $0.1 million toward the Minimum Royalty. 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.

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.

If AMF terminates the License Agreement under certain circumstances, we may be required to pay damages to AMF and AMF may have the right to terminate the license. In addition, if any of the royalties or other cash payments become due under the terms of the License Agreement, we may not have sufficient funds available to meet our payment obligations, which would allow AMF to terminate the License Agreement. Any termination or loss of rights (including exclusivity) under the License Agreement would materially and adversely affect our ability to develop and commercialize our r-SNM System, which in turn would have a material adverse effect on our business, operating results and prospects.

The License Agreement was amended twice in February 2014 in order to, among other things, include the field of the treatment of bladder and bowel 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 License Agreement allows AMF the right to use the AMF IP for non-commercial research, educational and scholarly purposes.

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 other approved SNM therapy offered by Medtronic, InterStim II and its predecessor, InterStim I. As our r-SNM System is 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 indications, such as OAB and UR, for which InterStim II is approved;
- 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 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 major U.S. insurers, including Medicare. We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. We are initially targeting the estimated top 1,000 physicians 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. 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 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 other implantable SNM devices. InterStim II is currently the only other implantable SNM device approved for commercial sale in the United States by the FDA. We also compete with other less invasive third-line treatments, such as BOTOX injections, a product sold by Allergan plc, PTNS, as well as more invasive surgical treatment options, and drugs for the treatment of OAB and FI. In addition, emerging businesses may be in the early stages of developing additional SNM devices or therapies designed to treat OAB or FI. We face competition from major medical device companies worldwide, including Medtronic, the maker of InterStim II. Many of these companies have longer, more established operating histories and significantly greater financial, technical, marketing, sales, distribution and other

resources than we do. We face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States. If one or more device manufacturers successfully develops a device that is more effective, better tolerated or otherwise results in a better patient experience, or if improvements in other third-line therapies make them more effective, easier to use or otherwise more attractive than our therapy, our ability to penetrate the third-line segment of the treatment market or maintain market share could be significantly and adversely affected, which would have a material adverse effect on our business, financial condition and results of operations.

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 more 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 to fabricate 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 which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, 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, full-body MRI conditional labeling, and an easy-to-use patient remote control. Finally, we designed and custom built a 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 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 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 introducing a second generation INS that extends the time between recharging sessions from once every one to two weeks to once a month, incorporating a modified header that allows us to connect our INS to an already implanted InterStim II lead, and over time, expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary-cell battery. Additionally, we intend to continue to pursue regulatory approval in the United States for OAB and UR.

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 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;
- address competitive counter moves advanced by Medtronic to secure and maintain customers;
- develop an effective and dedicated sales and marketing team to provide adequate education and training to potential users of 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 is approved to include OAB and UR 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 June 30, 2019, we had 244 employees. We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the 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 and 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 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 bladder or bowel dysfunction 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 bladder and bowel dysfunction in the United States, Europe and worldwide is increasing. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for 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 bladder or bowel dysfunction 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 bladder or bowel dysfunction 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.

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, or the Term Loan. In October 2018, we and Silicon Valley Bank entered into an amendment to the Loan and Security Agreement, or the Loan Agreement, as so amended. 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 but no principal amortization 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.

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. Our limited historical experience in foreign markets may not provide us with enough data to accurately predict increased future demand in the United States. 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 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 have sales and operations both inside and outside the United States, including a limited sales and marketing organization outside the United States. Our international sales strategy is to increase our presence in Europe, Canada, and Australia, which 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. 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 results 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 have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. Our policies and procedures may not be sufficient to ensure that our directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, or that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and

we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, 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. We urge the purchasers of our securities to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing 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, premarket clearance and approval, record keeping procedures, advertising and promotion, recalls and field safety corrective actions, postmarket surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury, postmarket 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.

We are also 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. The manufacturers that we work with are similarly subject to

periodic scheduled or unscheduled inspections of their facilities. Adverse findings during such inspections may impact our inventory and cause disruptions in product sales.

We may not receive the necessary clearances or approvals for expanded indications or modifications to our r-SNM System or for future product candidates, and failure to timely obtain necessary clearances or approvals for expanded indications or modifications to our r-SNM System or for future product candidates 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, 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 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 received regulatory approval in the United States through the PMA process for our r-SNM System for the treatment of FI on September 6, 2019, and have also submitted a PMA application for the treatment of OAB and UR. Any delay or failure to obtain regulatory approval in the United States for these additional indications could harm our business. Furthermore, even if we are granted these regulatory approvals, they may include significant limitations, which may limit the market for our device.

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 or modification may not be approved or cleared by the FDA. Any modifications to or expanded 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 or generate additional data to submit to the FDA, future product introductions or modifications or expanded indications for approved products could be delayed or canceled, which could adversely affect our ability to grow our business.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that the device is safe or effective for its intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of clinical studies or the interpretation of data from pre-clinical studies or clinical studies;
- serious and unexpected adverse device effects experienced by participants in clinical studies;
- the data from pre-clinical studies and clinical studies may be insufficient to support clearance or approval, where required;
- inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering clinical data or regulatory filings insufficient for clearance or approval.

The FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may impact our ability to modify our r-SNM System or introduce future products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain approvals once obtained. 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 postmarket 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 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. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or other similar regulatory authorities as reflected in the product's approved labeling. Physicians could use our r-SNM System on their patients in a manner that is inconsistent with the approved label. 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.

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 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 expand the indications for 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.

On September 6, 2019, we obtained FDA approval for our r-SNM System for the treatment of FI. We have also submitted a PMA application to obtain FDA approval for the treatment of OAB and UR. In order to obtain PMA approval for a device or expanded indications, the sponsor must meet the regulatory submission requirements of the FDA, which in many cases may require a PMA applicant to conduct well-controlled clinical studies designed to assess the safety and effectiveness of the product. Conducting clinical studies is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical studies but cannot be certain that the trials will ever result in commercial revenue. We may experience significant setbacks in clinical studies, even after earlier clinical studies showed promising results, and failure can occur at any time during the clinical study process. 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.

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 for OAB and UR. The data we collect from our pre-

clinical studies and clinical studies may not be sufficient to support FDA clearance or approval for OAB and UR, 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 for the treatment of OAB and UR.

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 expanded 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 may need to conduct additional clinical studies in the future 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 for expanded indications, including OAB and UR, or any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, the limit our ability to commercialize the product. Even if our r-SNM System is cleared or approved in the United States for expanded indications, including OAB and UR, 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.

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.

We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, registration, and listing of our r-SNM System. For example, we are required to submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

In addition, in order to obtain PMA approval for our r-SNM System for OAB and UR, we may be to subject to several conditions of approval, including a postmarket long-term study and extended follow-up of the premarket study cohort. Any failure to comply with the conditions of approval could result in the failure to obtain PMA approval for these indications or delay or withdrawal of PMA approval and the inability to market the device for the treatment of OAB and UR. 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 for OAB and UR or delay or withdrawal of PMA approval for these indications.

Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. We have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our 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 future PMA approvals or foreign regulatory approvals of future product candidates, new intended uses, including OAB and UR, 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 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 is 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 or result in it being adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with the manufacturing processes for our 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, 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 treatment guidelines for OAB, FI or UR change or the standard of care evolves, we may need to redesign and seek a new marketing authorization from the FDA for our r-SNM System.

If treatment guidelines for OAB, FI or UR 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.

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.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that our 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, 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, or make it more difficult to obtain approval for additional indications 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.

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 September 3, 2019, we wholly owned 23 issued U.S. patents and 56 issued foreign patents, and 19 pending U.S. patent applications and 53 pending foreign patent applications. We also license from AMF 27 issued U.S. patents and four pending U.S. patent applications, as well as 58 issued foreign patents and 14 pending foreign patent applications. Issued patents owned or used by us will expire between 2021 and 2039.

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 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 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. For example, on November 4, 2019, certain affiliates of Medtronic filed a lawsuit against us in the United States District Court for the Central District of California. The lawsuit asserts that our r-SNM System infringes certain patents owned by these affiliates of Medtronic and seeks customary remedies for patent infringement. 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 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, or 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, or 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 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 for additional indications or for 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 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;
- the results of any future legal proceedings; and
- other factors described in this "Risk Factors" section.

In addition, in the past, stockholders have initiated class action lawsuits against companies following periods of volatility in the market prices of these companies' common stock. Such litigation, if instituted against us, regardless of the merit or ultimate results of such litigation, could cause us to incur substantial costs and divert management's attention and resources.

We are 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 of 2002, as amended, or 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.

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 Securities Exchange Act of 1934, or the Exchange Act, as well as the listing requirements, or the Nasdaq Marketplace Rules, of 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 are in the process of undertaking 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, our internal control over financial reporting is perceived as inadequate or we are unable to produce timely or accurate financial statements, investors may lose confidence in 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 JOBS Act, depending on whether we continue 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, or 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. However, in light of the decision issued by the Court of Chancery in Sciabacucchi v. Salzberg, C.A. No. 2017-0931-JTL, invalidating similar provisions in the certificates of incorporation of three other Delaware corporations, we do not currently intend to enforce the foregoing federal forum selection provision unless the *Sciabacucchi* decision is appealed and the Delaware Supreme Court reverses the Chancery Court's decision. If the decision is not appealed or if the Delaware Supreme Court affirms the Chancery Court's decision, then we will seek approval by our stockholders to amend our certificate of incorporation at our next regularly scheduled annual meeting of stockholders to remove the federal forum selection provision.

Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to these provisions of our certificate of incorporation. These choice of forum provisions may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will rely in part on the research and reports that securities or industry analysts publish about us and our business. If one or more of the analysts who cover us downgrades our common stock or issues other unfavorable commentary or research the price of our common stock may decline. If one or more analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline and could result in the loss of all or part of your investment in us.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of 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 or incorporated by reference herein that are not statements of historical facts may be deemed to be forward-looking statements. We intend the forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, or other comparable terms intended to identify statements about the future. Forward-looking statements include, but are not limited to, statements about:

- our ability to maintain regulatory approvals for our r-SNM System and obtain regulatory approvals for our r-SNM System for additional indications;
- our ability to successfully commercialize our r-SNM System in the United States and internationally;
- commercial success, ability to capture market share and market acceptance of our r-SNM System;
- our ability to enhance our r-SNM System;
- our ability to achieve and maintain adequate levels of coverage or reimbursement for our r-SNM System;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize our r-SNM System;
- our ability to accurately forecast customer demand for our r-SNM System and manage our inventory;
- our ability to retain our senior management and hire other highly qualified personnel, including a sales force;
- developments and projections relating to our competitors and our industry, including competing products and therapies for the treatment of OAB, FI and UR;
- the accuracy of our estimates regarding expenses, future revenue and needs for additional financing;
- FDA or other United States or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States and international markets;
- the timing or likelihood of regulatory filings and approvals or clearances;
- any supplier shortages related to our r-SNM System or its components and any manufacturing disruptions which may impact our inventory supply as we expand our business;
- our ability to establish and maintain intellectual property protection for our r-SNM System or avoid claims of infringement of third party intellectual property;
- the volatility of the trading price of our common stock.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions described under the section entitled "Risk Factors" and elsewhere in this prospectus or any accompanying prospectus supplement, and the documents incorporated by reference in this prospectus. We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances described in this prospectus or any accompanying prospectus supplement, and the documents incorporated by reference herein may not occur and actual results could differ

materially and adversely from those anticipated or implied in the forward-looking statements contained in this prospectus or any accompanying prospectus supplement, and the documents incorporated by reference herein.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements may never be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus, any accompanying prospectus supplement, the documents incorporated by reference herein and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement on Form S-3, of which this prospectus is a part, 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.

Statistical Data

We obtained the industry, statistical and market data, including our general expectations, market position and market opportunity, in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. All of the market data used in this prospectus involves a number of assumptions and limitations. While we believe that the information from these industry publications, surveys and studies is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

USE OF PROCEEDS

We will retain broad discretion over the use of the net proceeds from the sale of the securities offered hereby. Except as described in any applicable prospectus supplement we have authorized for use in connection with a specific offering, we currently intend to use the net proceeds from the sale of the securities offered by us hereunder, if any, for working capital and general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no current commitments or agreements with respect to any acquisitions as of the date of this prospectus. We will set forth in the applicable prospectus supplement our intended use for the net proceeds received from the sale of any securities sold pursuant to the prospectus supplement. Pending the use of the net proceeds from any such offering, we may invest the net proceeds in investment grade, short-term interest-bearing obligations, such as money-market funds, certificates of deposit, or direct or guaranteed obligations of the United States government, or hold the net proceeds as cash.

We will not receive any proceeds from any sale of the shares of our common stock offered by the selling stockholders. The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of their shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares of common stock covered by this prospectus, including all registration and filing fees and fees and expenses of our counsel and accountants.

BUSINESS

Overview

We are a medical technology company that has developed and is commercializing an innovative and minimally invasive implantable neurostimulation system for sacral neuromodulation, or SNM, therapy. SNM therapy is primarily used to treat patients with urinary urge incontinence, or UUI, and urinary urgency frequency, or UUF, together referred to as overactive bladder, or OAB, fecal incontinence, or FI, and non-obstructive urinary retention, or UR. We believe our proprietary SNM system, or our r-SNM System, has the potential to disrupt and grow the approximately $650 million, as of 2018, global SNM market, which is currently served by Medtronic plc, or Medtronic, as a single participant.

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 bladder and bowel 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 is 60% smaller than the InterStim II System, or InterStim II, which is the only other approved SNM product and is marketed by Medtronic.

Our r-SNM System received premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, on September 6, 2019 for the treatment of FI, and we have also submitted a PMA application to the FDA for OAB and UR. We also have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR.

We have a growing body of compelling clinical evidence that demonstrates the safety, effectiveness, and sustained benefits of our r-SNM System including two clinical studies relating to our r-SNM System: a European study, RELAX-OAB, and a U.S. pivotal study, ARTISAN-SNM. In June 2018, we completed the enrollment and implantation of 129 patients with UUI for our ARTISAN-SNM pivotal study. As of July 2019, all patients in our ARTISAN-SNM study have completed their six-month endpoint and have also completed one-year post-implant follow up. These patients were 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. In our clinical work and our investigator-initiated case series, and through our commercial efforts in Europe and Canada we have implanted approximately 500 patients to date.

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

- The study has passed the six-month primary endpoint and completed one-year follow up;
- 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 one year, 115 of the 129 implanted patients, or 89%, continued to be therapy responders;
- At six months, 93% of all implanted patients reported being "satisfied" with the therapy, and at one year, 93% of all implanted patients continued to report being "satisfied" with the therapy;
- No serious device-related adverse events have been reported.
- We submitted the complete six-month results of the study to the FDA as an amendment to our previously submitted PMA, and intend to follow patients out to two years; and
- On October 24, 2019, we submitted one-year follow up data to the FDA as part of our annual investigational device exemption, or IDE, update process.

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 evaluated to determine if they were therapy responders, which was defined as showing at least a 50% reduction in the number of average leaks or voids per day or a reduction to less than eight voids per day, in each case on a three-day bladder diary, at various times post-implant. We are following patients out to two years in this study and may follow patients out to five years at selected study sites.

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

- The study has completed one-year follow-ups and two-year follow-ups;

- 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;
- At 12 months, 84% of test responders and 77% of all implanted patients were “very” or “moderately” satisfied with the therapy provided by our r-SNM System; 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 bladder and bowel 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 or accidental leakage from the rectum.

Symptoms of bladder and bowel 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 bladder and bowel 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 bladder and bowel 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 bladder and bowel dysfunction that are treated with SNM therapy have either UUI alone, 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, or BOTOX, injections and percutaneous tibial nerve stimulation, or 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, offered by Medtronic. We believe that our r-SNM System is the first and only system for SNM therapy with a rechargeable implantable neurostimulator, or 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. We also received CE Mark for our r-SNM System for 1.5T/3.0T MRI full-body conditional labeling on February 22, 2019 and FDA approval for our r-SNM System for 1.5T MRI full-body and 3.0T head conditional labeling on September 6, 2019. Our r-SNM System allows full-body MRI scans and head scans under certain conditions, 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 a body part other than the head, which is currently required for patients implanted with InterStim II. This full-body MRI 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 to fabricate 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, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, 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 clinician programmer that guides the implanting physician through electrode placement and stimulation programming.

We intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System. Our goals include introducing a second generation INS that extends the time between recharging sessions from once every one to two weeks to once a month, incorporating a modified header that allows us to connect our INS to an already implanted InterStim II lead, and over time, expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary cell battery.

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 one to 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 45,000 patient implants, including an estimated 10,000 patients receiving 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 bladder or bowel 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 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 major U.S. insurers, including Medicare. We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. We are initially targeting the estimated top 1,000 physicians 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. In addition, we plan to expand our current sales team into select international markets.

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

Our Success Factors

We believe that continued growth of our company will be driven by the following success factors:

- ***Large and growing SNM market with established coverage and reimbursement.*** SNM treatment for OAB, FI, and UR is a well-established therapy. Since the first FDA-approved SNM device, the InterStim I System, was introduced in 1997, we estimate hundreds of thousands of patients have been implanted worldwide with such system and its successor InterStim II. In 2018, we believe that approximately 45,000 patients were implanted with SNM therapy, including an estimated 10,000 patients receiving replacement implants, corresponding to an approximately $650 million global annual addressable SNM market and approximately 8% year-over-year growth. With the global SNM market currently estimated to be approximately one percent penetrated, we believe that the introduction of a new and highly differentiated SNM solution has the potential to grow the market in excess of historical size and growth rates. In addition, because SNM therapy has been widely used in patients for over 20 years in the United States, which we believe makes up nearly 90% of the sales in the global SNM market, reimbursement codes and payments are well-established and the procedure is covered by most major U.S. insurers.

- ***Long-term solution offering material benefits to patients, physicians, and payors***. 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 InterStim II, which is not a rechargeable system. We believe a rechargeable system will significantly improve a patient's experience and reduce the risks of surgery and associated infections. In addition, by reducing the number of replacement surgeries, physicians and facilities can utilize their resources more efficiently. Our r-SNM System also allows full-body MRI scans under certain conditions, 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 a body part other than the head, which is currently required for patients implanted with InterStim II. Finally, we believe that our technology has the potential to significantly reduce overall costs to the healthcare system. In 2016, we commissioned a study, which 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.

- ***Significant competitive and functional advantages over the only other approved SNM device***. We believe that our r-SNM System's innovative and proprietary design offers significant competitive and functional advantages over InterStim II. Our proprietary method of combining ceramic and titanium to fabricate 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 which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, 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 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.

- ***Strong clinical data***. We have a growing body of compelling clinical evidence that demonstrates the safety and effectiveness of our r-SNM System. In our clinical work to date, we have implanted 180 patients in the United States and Europe. Our ARTISAN-SNM pivotal study is evaluating 129 patients with UUI. In the six-month results, therapy response rate was 90% for all patients, and at one year the response rate was maintained at 89% for all patients. We submitted the complete six-month results of the study to the FDA as an amendment to our previously submitted PMA. Our European study, RELAX-OAB, evaluated 51 patients that suffered from UUF and UUI. The therapeutic response 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. We intend to follow patients for at least two years for both of our clinical studies. We believe clinical data is important and will be key to driving broad-based adoption of our r-SNM System.

- ***Substantial sales and clinical field teams***. We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. We used the time between our initial public offering

and the commercial launch of our r-SNM System in the United States to recruit and hire, then rigorously train, a highly qualified sales and clinical staff. We anticipate that this investment in our sales force will enable us to compete effectively and gain market share, as we expect relationships, expertise and patient outcomes will be important factors in the widespread adoption of our r-SNM System.

- ***A deep understanding of our target market with a sole focus on SNM***. We formed our company by assembling an experienced team with significant in-depth knowledge of our target market. From the outset, we spent significant time understanding the unmet needs of patients and physicians through patient field studies and early engagement of physicians and key opinion leaders. By utilizing this market knowledge and focusing solely on SNM, we have been able to navigate the development and regulatory requirements for our r-SNM System in an efficient manner. Since we commenced operations in late 2013, we have received a PMA for FI in the United States from the FDA and marketing approval in Europe, Canada, and Australia for OAB, FI, and UR. We have also submitted a PMA application for OAB and UR to the FDA. This pure-play SNM focus also allows us to efficiently manage our research and development activities to further innovate and enhance our r-SNM System.

- ***Comprehensive and broad intellectual property portfolio***. Our r-SNM System is supported by a nucleus of issued patents and patent applications that we license from AMF pursuant to the License Agreement. In addition to that nucleus, we have created a substantial portfolio of wholly owned intellectual property, which includes patents, know-how and trade secrets that are embodied by our r-SNM System. As of September 3, 2019, we wholly owned 23 issued U.S. patents and 56 issued foreign patents, and 19 pending U.S. patent applications and 53 pending foreign patent applications. We also license from AMF 27 issued U.S. patents and four pending U.S. patent applications, as well as 58 issued foreign patents and 14 pending foreign patent applications. Issued patents owned or used by us will expire between 2021 and 2039.

- ***Experienced management team***. Our senior management team has over 140 years of combined experience in the medical technology industry. They have a track record of successfully bringing products to market, with significant expertise in development, regulatory approval and commercialization activities.

Our Strategy

Our goal is to become a global leader in providing an effective and long-term solution to patients with OAB and FI. To achieve this goal, we are pursuing the following strategies:

- ***Obtain FDA approval of our r-SNM System for OAB and UR***. On September 6, 2019, we received FDA approval for our r-SNM System for the treatment of FI, and we are also seeking FDA approval for the treatment of OAB and UR. In June 2018, we completed the enrollment and implantation of 129 patients with UUI for our ARTISAN-SNM pivotal study. On December 3, 2018, we submitted a new PMA application for OAB and UR to the FDA which was officially accepted by the FDA on December 10, 2018. This PMA was initially based on safety and effectiveness data from a review of clinical literature reporting on the InterStim system and a review of technical test data on our r-SNM System. In this PMA filing, in addition to published clinical literature reporting on the InterStim system, we submitted one-year follow-up data from our 51-patient RELAX-OAB European postmarket clinical follow-up study to support the PMA. Since the original PMA submission in December 2018, we have submitted various amendments to the FDA in support of the PMA. These amendments included the clinical results on the first 60 patients to reach their six-month primary endpoint from our ARTISAN-SNM pivotal study. In addition, we filed amendments to include data in support of full-body MRI labeling and complete six-month clinical data on all implanted subjects from the ARTISAN-SNM study.

- ***Continue to promote awareness of our r-SNM System among healthcare providers***. We believe that of the approximately 47,000 physicians addressing OAB and FI in the United States, only approximately 2,000 are trained to perform, or are actively performing, SNM procedures. In the near-term, we plan to focus on building and maintaining support from key opinion leaders while increasing awareness of our r-SNM System among the estimated 1,000 physicians who represent a majority of the implant volume in the United States. We intend to help physicians in their direct-to-patient outreach, and may in the future engage in our own direct-to-patient marketing initiatives. We believe this will expand the number of patients undergoing SNM procedures.

- ***Continue to develop a commercialization infrastructure with a dedicated direct sales team***. We intend to focus the significant majority of our sales and marketing efforts in the United States since we believe that nearly 90% of the annual global SNM sales are generated in this market. Our priority is to target high-volume implant centers. We hired

and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. In addition, we intend to expand our current sales team into international markets.

- ***Continuously innovate to introduce enhanced SNM product offerings and pursue expanded indications***. We intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System. Our goals include introducing a second generation INS that extends the time between recharging sessions from once every one to two weeks to once a month, incorporating a modified header that allows us to connect our INS to an already implanted InterStim II lead, and over time, expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary cell battery.

- ***Further penetrate our initial target market by promoting patient and practice awareness***. Currently, we estimate that approximately one percent of the four million OAB and FI patients that make up the annual global addressable SNM market are implanted with an SNM device. We believe that there are several factors that influence this light penetration of the market. First, although patients may be familiar with SNM as an alternative therapy, patients who elect not to have the procedure do so because of the limitations of the existing technology, such as the potential for multiple INS replacement surgeries and the large device size. Second, we believe there is a large potential patient population that suffers from OAB and/or FI and is unaware of third-line therapies such as SNM. We believe that a very low percentage of physician specialists that treat patients with symptoms of OAB and/or FI are actively performing SNM procedures. We intend to educate physicians that are unfamiliar with or do not utilize SNM therapy on the benefits on SNM therapy and the advantages of our r-SNM System. We also intend to increase physician awareness through engagement and continued publication of scientific data in peer reviewed journals. Further, we intend to engage individuals who suffer from OAB and FI symptoms through direct patient outreach.

Our Market

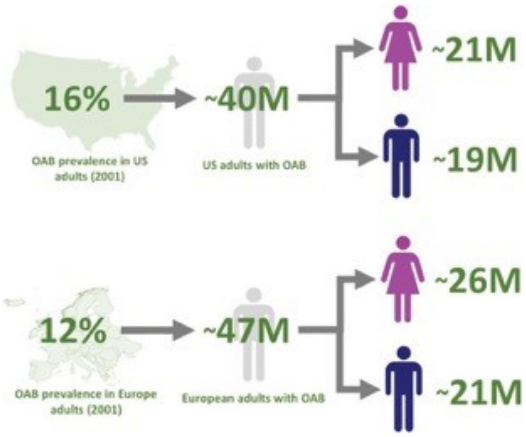
We believe our initial target market consists of approximately four million adults in the United States and Europe who suffer from symptoms of either bladder or bowel dysfunction, who have already failed first and second line therapies and are readily treatable with, and eligible candidates for, SNM 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 are initially focusing on the United States and Europe due to larger overall market size and greater prevalence of bladder and bowel 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 45,000 patient implants, including an estimated 10,000 patients receiving 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.



Although the study and surveys date back approximately twenty years, we believe these surveys are still representative of the prevalence of OAB 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, or 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, or PQRS, which was introduced by the Center for Medicaid and Medicare Services, or 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, or 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 or accidental leakage from the rectum. Stimulation of the sacral nerves can reduce incontinence episodes, urgency, and frequency in people suffering from FI, and is an approved therapy for the treatment of FI in the United States and Europe. Moreover, a significant population of people suffering from FI also exhibit symptoms of OAB. SNM therapy can alleviate symptoms in patients suffering from either or both OAB and FI. 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

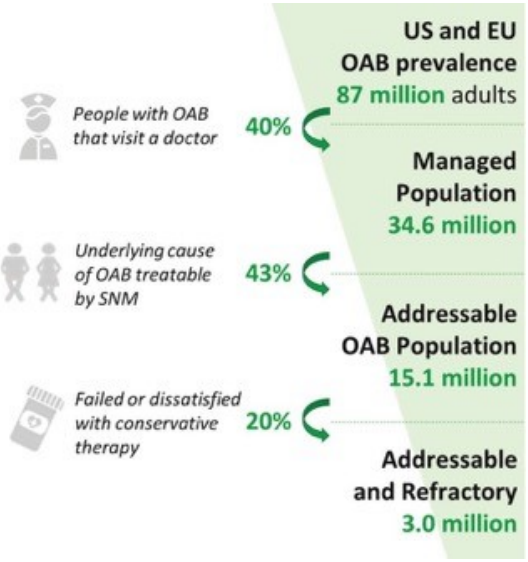
In the United States, of the approximately 40 million adult patients with symptoms of OAB, we believe that approximately 15.9 million seek medical attention, with UUI patients more frequently consulting with a physician. Similarly, in Europe, of the approximately 47 million adult patients with symptoms 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. SNM therapy cannot be used to treat every person who suffers from symptoms of OAB. To estimate the OAB population addressable with SNM therapy, we do not account for people suffering from symptoms of OAB who do not seek medical attention.

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.



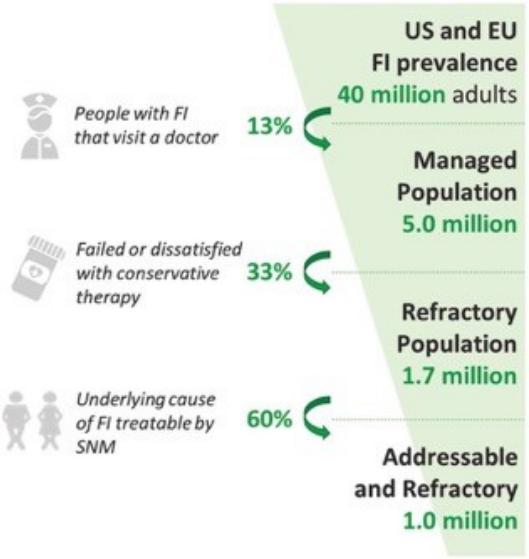
Fecal Incontinence

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. SNM therapy cannot be used to treat every person who suffers from symptoms of FI. To estimate the FI population addressable with SNM therapy, we do not account for people suffering from symptoms of FI who do not seek medical attention.

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 other 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 hundreds of thousands of patients worldwide, with a majority of all implants having taken place in the United States. In 2018, approximately 45,000 patients were implanted with these systems, including an estimated 10,000 patients receiving replacement implants.

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 bladder and bowel dysfunction. We currently have marketing approvals in Europe, Canada, and Australia for UUI, UUF, UR, and FI, and received a PMA from the FDA for FI on September 6, 2019. We have also submitted a PMA application to the FDA for for OAB and UR.

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 one to 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.

Implantable Neurostimulator

External Components for Patient

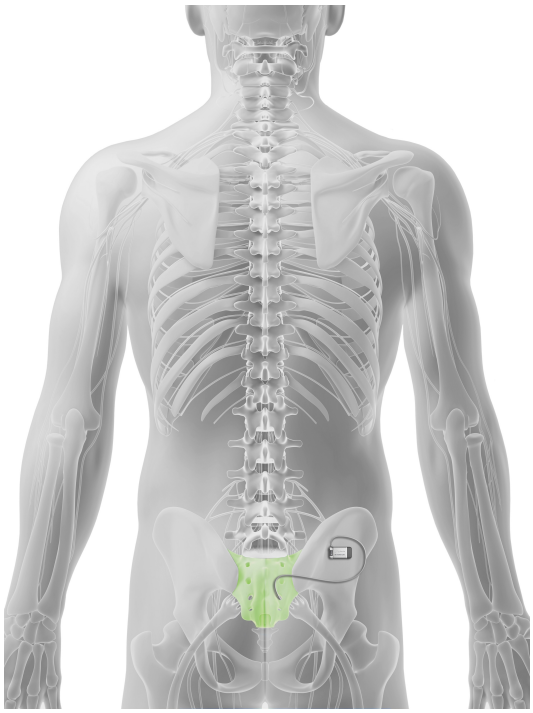
- Wireless charging device, which allows transcutaneous charging of the INS. The charger uses an easy to understand combination of visual, audio and haptic indicators to provide information about the charging status. Further, it has the ability to be held into position by an adhesive fixation device 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.

Wireless Charging Device

Patient Remote Control

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**. The battery is designed to last 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 approximately 60% smaller than and half the weight of InterStim II.
- **Constant current**. Our r-SNM System delivers constant current stimulation, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, 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 clinician programmer guides the implanting physician through electrode placement and stimulation programming and enables physicians to access key data from the patient's INS.
- **Full-body MRI scan labeling.** Our r-SNM System allows for full-body MRI scans. 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 a body part other than the head, which is currently required for patients implanted with InterStim II. Additionally, 1.5T full-body MRI scans can be done in normal operating mode with no additional whole-body specific absorption rate limitation, allowing efficient MRI scans to be performed on any body part.

Overview of our External Trial System

Our external trial system, or 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, and in September 2019, we received FDA approval 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 bladder and bowel dysfunction. This therapy is not intended for patients with a mechanical obstruction such as benign prostatic hyperplasia, a tumor, or urethral stricture. Further, the therapy is not indicated for pregnant women, or pediatric use.

SNM therapy for 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 bladder or bowel 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 have 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 320 patients being treated in our investigator-initiated case series and commercially.

In June 2018, we completed the enrollment and implantation of 129 patients with UUI for our ARTISAN-SNM pivotal study. As of July 2019, all patients have completed their six-month primary endpoint and have also completed one-year post-implant follow up. These patients were evaluated at 14 centers in the United States and five centers in Europe. Of the total 129 patients, 119 were directly implanted without undergoing any external trial period. We have determined the study's primary endpoint to be the percentage of implanted patients 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.

Patients were evaluated as being either "therapy responders" or "therapy failures" based on their therapy response at follow-up visits. "Therapy responders" were defined as showing at least a 50% reduction in urgency leaks on a three-day bladder diary. At six months, the therapy response rate was 90% for all patients, and 93% of all patients were "satisfied" with the therapy. We submitted the complete six-month results of the study to the FDA as support for our PMA, and intend to follow patients out to two years.

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.

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, or AEs, or serious device-related AEs, in any of our clinical studies or the 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.

ARTISAN-SNM Pivotal Study

Overview

We have sponsored the ARTISAN-SNM study, a multicenter, single-arm, unblinded prospective study. The study is designed to evaluate the safety and effectiveness of our r-SNM System as an aid in the treatment of symptoms of UUI in order to obtain a PMA in the United States.

The study began in December 2017 and is being performed at 14 centers around the United States and five in Europe. As of June 2018, we implanted 129 patients and completed the enrollment process for this study, and as of July 2019 all patients have completed their six-month primary endpoint and have also completed one-year post-implant follow up.

All 129 implanted patients had a primary diagnosis of UUI with at least four urgency leaks on a three-day bladder diary. We believe a three-day bladder diary is appropriate because the clinical literature supports the validity of a three-day bladder diary and the guidelines of the American Urology Association confirm the utility of a three-day bladder diary in evaluating OAB. Study patients had also failed, were contraindicated or refractory for, first- and second-line therapies, such as behavioral modification and medication.

Of the total 129 patients, 119 were directly implanted without undergoing any external trial period. 127 were females and two were males with an average age of 59 years old, ranging from 21 to 86 years old. In addition, the average body mass index, or BMI, for the 129 patients was 31, ranging from a minimum of 18 to a maximum of 58. The average symptoms in the implanted patients were 5.6 urgency leaks per day and 10.5 voids per day. Approximately 24% of the patients had previously been treated with other third-line therapies for UUI, such as BOTOX injections and/or PTNS.

Patients were evaluated as being either "therapy responders" or "therapy failures" based on their therapy response at follow-up visits. "Therapy responders" were defined as showing at least 50% reduction in urgency leaks on a three-day bladder diary. We have determined the primary effectiveness endpoint for the study to be the percentage of patients that are therapy responders at six months post implant. The study is also measuring voids per day on a three-day bladder diary, device performance metrics, quality of life improvement on the ICIQ-OABqol questionnaire, AEs, patient satisfaction with the therapy and recharging experience, medication usage, healthcare utilization, and bowel function based on questionnaires. We are currently in the follow-up portion of this study and will record data on these measures at 3, 6, 12, 18 and 24 months for all patients.

Six-Month and One-Year Study Results

Six-month and one-year results are available for all 129 patients of which 116 are therapy responders at six months and 115 are therapy responders at one year, as presented below.

Therapy Response

Of the 129 implanted patients, 124 completed the one-year follow-up and 5 were exited prior to one year. At the six-month follow-up, 116 of 129 implanted patients, or approximately 90%, were therapy responders. Of the therapy responders, 93, or approximately 80%, had at least a 75% reduction in urgency leaks and 39 of the therapy responders, or approximately 34%, were completely dry, as illustrated in the table below.

At the one-year follow-up, 115 of 129 implanted patients, or approximately 89%, were therapy responders. Of the therapy responders, 88, or approximately 77%, had at least a 75% reduction in urgency leaks and 33 of the therapy responders, or approximately 29%, were completely dry, as illustrated in the table below.

ARTISAN-SNM—Therapy Response Rate

	All Patients 6 Month	All Patients One Year
Number of Patients (#)	129	129
Therapy Responders (# (%) of patients)		
UUI Responders	116 (90%)	115 (89%)
UUI Responder Details (# (%) of responders)		
50-74% improvement in the number of average urgency leaks per day	23 (20%)	27 (23%)
75-99% improvement in the number of average urgency leaks per day	54 (46%)	55 (48%)
100% improvement in the number of average urgency leaks per day	39 (34%)	33 (29%)

All patients showed significant improvement in their urgency leaks at six months and one year. Significant improvement in urgency leak reduction was also observed in all patients. Urgency leaks of all patients were reduced from 5.6 (±0.3) per day at baseline to 1.2 per day (±0.2) at six months and one year, as illustrated in the table below.

ARTISAN-SNM—UUI Symptoms

	All Patients		
	Baseline	6 Month	12 Month
Number of Patients (#)	129	126	124
UUI Symptoms			
Leaks Per Day	5.6	1.2	1.2

Patient Satisfaction and Recharging Experience

At six months, 93% of all patients were “satisfied” with r-SNM therapy. Additionally, 92% of all patients reported that they would undergo r-SNM therapy again. Charging was “acceptable” for 98% of all patients. 95% of all patients reported that it was “easy” to recharge their r-SNM System.

At one year, 93% of all patients were “satisfied” with r-SNM therapy. Additionally, 92% of all patients reported that they would undergo r-SNM therapy again. Charging was “acceptable” for 96% of all patients. 89% of all patients reported that it was “easy” to recharge their r-SNM System.

Safety

There have been no unanticipated AEs or serious AEs, and no AEs have been reported related to recharging our r-SNM System.

Device-related AEs were reported, which occurred in 14 patients, or 11% of all patients. The most common device-related AE was discomfort due to stimulation, which was reported by 7 patients as 7 separate events. All of these events were

successfully resolved with reprogramming the stimulation settings. Pain at the implant site occurred in only 2 of 129 patients, or less than 2%, and the pain resolved without surgical intervention. One incident of lead migration occurred after implantation in a patient who did not adhere to post-procedure care instructions relating to limiting physical activity. The lead was successfully repositioned in this subject. There was one incident of lead fracture, and the lead was successfully replaced in this patient.

Exited Patients

We explanted our r-SNM System in four patients: one patient was explanted four weeks after implantation due to incision site infection, a second patient was explanted approximately 4 months after implantation due to pain unrelated to the device or procedure, and two patients were explanted between six and 12 months after implantation due to insufficient efficacy. One patient died during the study (approximately 145 days after implant) due to health complications unrelated to the study or device.

RELAX-OAB Study

Overview

We sponsored the RELAX-OAB study, a multicenter, prospective, single-arm, unblinded study conducted as a postmarket follow-up after receiving a CE Mark in Europe in 2016 to evaluate the safety and effectiveness of our r-SNM System. The study began in June 2016 and was performed at seven centers around Europe. Patients in this study were implanted with our r-SNM System in a single-stage implant procedure without any external trial period, which is in contrast to the general practice where patients are typically screened for suitability with an external test stimulator before proceeding to the full implant.

We implanted and evaluated 51 patients that had a primary diagnosis of OAB, with UUI indicated by a minimum of two incontinence episodes over three days, and UUF indicated by at least eight voids per day, in each case as shown on a three-day bladder diary. Study patients had also failed, been contraindicated or refractory for, first- and second-line therapies, such as behavioral modification and medication. Of the total 51 patients, 38 were females and 13 were males, with an average age of 51 years old, ranging from 21 to 77 years old. In addition, the average BMI for the 51 patients was 27, ranging from a minimum of 16 to a maximum of 38. Further, 98% of the patients had UUF, with an average of 14.7 (±0.9, standard error) voids per day, and 73% had UUI, with an average of 9.6 (±0.8, standard error) leaks per day. Approximately 51% of the patients had previously been treated with other third-line therapies, such as BOTOX injections and/or PTNS.

Patients were evaluated as being “test responders” or “test failures” based on their therapy response within the first month. 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 the end of the one-month period, 34 of the 48 patients, or 71%, were determined to be test responders, and 14 of the 48 patients were determined to be test failures.

The primary effectiveness endpoint was mean change in the International Consultation on Incontinence Modular Questionnaire, or ICIQ-OABqol, score as compared to baseline, a standard measure of quality of life for OAB patients. ICIQ-OABqol is a validated questionnaire that measures a patient’s quality of life based on a patient’s reporting on a 0 to 100 scale, with zero representing the lowest quality of life and 100 representing the best quality of life. This same questionnaire was also used by Medtronic in the InSite study to evaluate the impact of SNM therapy of quality of life.

Additional performance measures evaluated the percentage of patients that were therapy responders, as well as AEs, patient satisfaction, and recharging experience as measured on a questionnaire. We recorded data on the patients for the primary effectiveness endpoint and the additional performance measures at three months, six months and 12 months for test responders and all implanted patients. We will continue to follow these patients until two years after implantation and may follow patients out to five years at selected study sites.

Study Results

The three-month results and the 12-month results were published in the peer reviewed *Journal of Neurourology and Urodynamics* in February 2018 and January 2019, respectively. The study met the primary endpoints at three months. Of the 51

implanted patients, 48, 46, and 43 completed the three-, six-, and 12-month follow-ups, respectively, with no major protocol deviations. The remaining patients at each of these follow-ups were excluded because of major protocol deviations or due to explants as described below under “Explants.”

Quality of Life

At three months, patients experienced clinically meaningful improvements in quality of life. Compared to the baseline of 55.2 (±3.8, standard error), the composite ICIQ-OABqol score increased by an average of 27.3 points in test responders (±3.6, standard error) and 21.8 points in all patients at three months, a substantial improvement from the clinically minimally important difference of 10 points. Additionally, scores on concern, coping, sleep, and social interaction subscales of the ICIQ-OABqol also showed significant improvements. Clinically meaningful quality of life improvements were sustained for test responders at six months and 12 months in the composite quality of life score and all subscale scores, as illustrated in the table below.

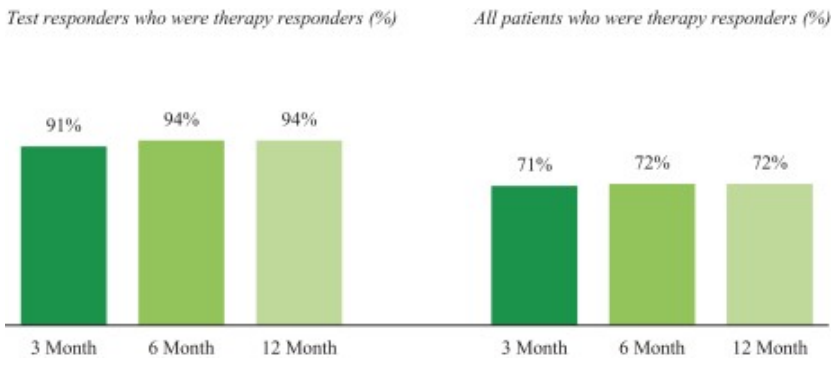
RELAX-OAB-ICIQ-OABqol-Change in Score Compared to Baseline for Test Responders

	3 Month	6 Month	12 Month
Number of Patients (#)	**34**	**34**	**32**
Composite Quality of Life Score			
Total Score (#)	+27.3	+25.8	+22.9
Subscales			
Concern	+27.5	+25.3	+24.0
Coping	+33.5	+32.5	+26.6
Sleep	+25.1	+23.5	+19.1
Social Interaction	+19.3	+18.1	+19.0

OAB Therapy Response Rate

Patients were considered OAB therapy 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. Any patient that had both UUI and UUF symptoms that showed a therapy response in both UUI and UUF was counted as two OAB therapy responders. Of the 34 test responders, 31 patients, or 91%, continued to respond to the therapy at three months. For all patients, 34 of 48, or 71%, were therapy responders at three months. Therapy response continued to be robust at six months and 12 months. 94% and 94% of test responders were therapy responders at six months and 12 months, respectively, and 72% and 72 % of all patients were therapy responders at six months and 12 months, respectively. The following table provides a summary of OAB therapy response for test responders who were therapy responders and for all patients who were therapy responders (in percentages).

RELAX-OAB-OAB Responder Rate



UUI Response

Patients were considered UUI responders if they experienced at least a 50% reduction in the number of average leaks per day on a three-day bladder diary. Test responders had significant improvements in their leaks at three months. Of the 28 test responders with UUI, 21 patients, or 75%, were responders based on their UUI symptoms at three months, including 64% experiencing at least a 75% reduction in leaks per day. At such time, leaks for test responders decreased from 8.3 (± 0.8) per day at baseline to 1.9 per day (± 0.5). 25% of test responders were completely dry at three months. Test responder patients continued to experience significant reductions in leaks at six months and 12 months, as provided in the table below.

Significant improvement of UUI symptoms was also seen in all patients. 30 of 48 patients, or 64%, were responders based on their UUI symptoms at three months. Compared to the baseline of 9.6 leaks per day for all patients, leaks per day reduced by 5.9 (±0.8) at three months. Significant reductions in leaks per day were maintained at six months and 12 months, as illustrated in the table below.

RELAX-OAB-UUI Responder Rate

The table below illustrates the number of leaks per day at three, six, and 12 months, compared to the baseline.

RELAX-OAB-UUI Symptoms

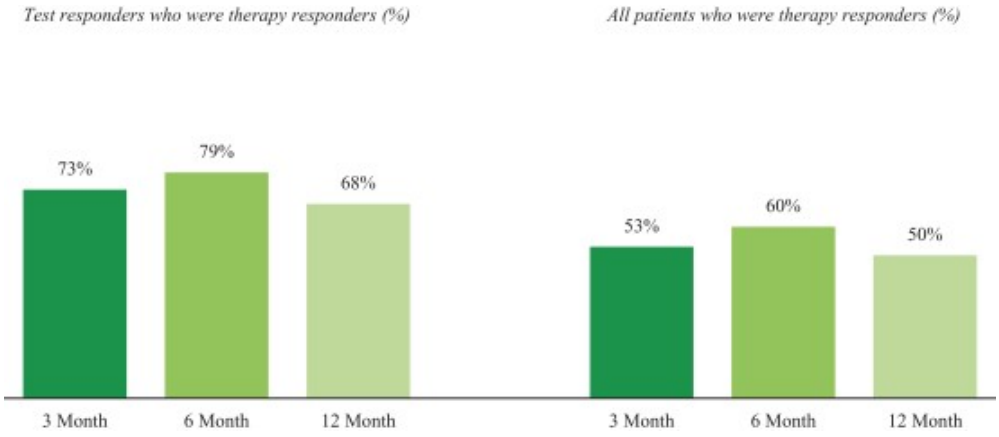
	Test Responders				All Patients			
	Baseline	3 Month	6 Month	12 Month	Baseline	3 Month	6 Month	12 Month
UUI Symptoms								
Number of Patients (#)	28	28	28	26	36	36	35	32
Leaks Per Day	8.3	1.9	2.2	1.8	9.6	3.7	3.9	3.8

UUF Response

Patients were considered UUF responders if they experienced at least a 50% reduction in the number of average voids per day or a reduction to less than eight voids per day, in each case on a three-day bladder diary. Test responders had significant improvements in their voiding episodes at three months. 24 of the 33 test responders, or 73%, were responders based on a reduction in UUF symptoms, including 61% of test responders that achieved normal levels of voiding, or less than eight voids per day. Compared to the baseline of 14.3 (± 1.1) voids per day, at three months voids per day for test responders were reduced by 6.6 voids per day to 7.7 (± 1.0). Reductions in voids per day continued for test responders at six months and 12 months, with average voids per day of 7.5 and 8.0 respectively, as illustrated in the table below.

Significant improvements of UUF symptoms were also seen in all patients. 25 of 47 patients, or 53%, were responders based on their UUF symptoms, while 70% of all patients experienced at least a 50% reduction in severe and desperate urgency episodes. Compared to the baseline of 14.7 (± 1.1) voids per day, at three months, voids per day for all patients decreased by 5.5 voids per day to 9.2 (± 0.3). At six and 12 months, all patients showed the reduction in voids per day was maintained, as illustrated in the table below.

RELAX-OAB-UUF Responder Rate



The table below illustrates the number of voids per day at three, six, and 12 months, compared to the baseline.

RELAX-OAB- UUF Symptoms

	Test Responders				All Patients			
	Baseline	3 Month	6 Month	12 Month	Baseline	3 Month	6 Month	12 Month
UUF Symptoms								
Number of Patients (#)	33	33	33	31	50	47	45	42
Voids Per Day	14.3	7.7	7.5	8.0	14.7	9.2	8.6	9.4

Patient Satisfaction and Recharging Experience

At three months, 82% of test responders and 77% of all patients were “very” or “moderately” satisfied with our r-SNM System. Additionally, 88% of test responders and 77% of all patients reported that they would“definitely” or “probably” recommend r-SNM therapy to friends. Patient satisfaction with the therapy continued at six months and 12 months, with 82% and 84% of test responders satisfied with therapy, respectively, as illustrated in the table below.

RELAX-OAB-Patient Satisfaction

	Test Responders			All Patients		
	3 Month	6 Month	12 Month	3 Month	6 Month	12 Month
Number of Patients (#)	34	34	32	48	46	43
How satisfied are you with the SNM therapy for the treatment of your OAB?						
Very or Moderately satisfied	82.4%	82.4%	84.4%	77.1%	78.3%	76.7%
Slightly satisfied	5.9%	2.9%	6.3%	6.3%	2.2%	9.3%
Neutral	2.9%	0.0%	3.1%	6.3%	0.0%	4.7%
Slightly dissatisfied	2.9%	8.8%	0.0%	4.2%	10.9%	0.0%
Moderately or Very dissatisfied	5.9%	5.9%	6.3%	6.3%	8.7%	9.3%
How likely are you to recommend SNM therapy to a friend?						
Definitely or Probably	88.2%	82.4%	85.7%	77.1%	76.1%	78.9%
Possibly	5.9%	11.8%	7.1%	10.4%	13.0%	7.9%
Neutral	0.0%	0.0%	3.6%	4.2%	2.2%	7.9%
Possibly Not	2.9%	2.9%	0.0%	2.1%	4.3%	2.6%
Probably or Definitely Not	2.9%	2.9%	3.6%	6.3%	4.3%	2.6%

At 12 months, 100% of all patients were able to charge their device. The duration of charging was “moderately” or “very” acceptable for 100% of test responders and 98% of all patients. 91% of test responders and 83% of all patients reported that it was “moderately” or “very” easy to recharge their r-SNM System.

Safety at 12 months

There were no unanticipated AEs reported as it related to the recharging of our r-SNM System. There were reported 20 device-related AEs which occurred in 13 patients, or 25% of all patients. Seven of the 20 AEs, or 35%, occurred during the two-week period after implant. The most common device-related AE was undesirable or uncomfortable stimulation, which was reported by 10 patients as 13 separate events. All of these events were successfully resolved with reprogramming. Pain at the implant site occurred in one of 43 patients, or 2%, and this was also successfully addressed with reprogramming. One incident of lead migration occurred between three and six months after implantation in a patient who engaged in a high-intensity athletic activity that required heavy lifting. There were no reports of lead fracture. There was one procedure-related serious AE, described below under “Explants.”

Therapy Response in Test Failures

Of the patients that were test failures, one of 11, or 9%, was a therapy responder at 12 months with at least 50% reduction in leaks. However, six of the 11 test failures, or 55%, reported being “very” or “moderately” satisfied with SNM therapy. Six of 11, or 55%, test failures had clinically significant improvements on the composite ICIQ-OABqol score.

Explants

We explanted our r-SNM System in one patient three weeks after implantation due to infection at the INS site, a procedure-related SAE. Additionally, two other patients were explanted between six and 12 months post-implant due to lack of efficacy.

Southampton Fecal Incontinence Case Series

Overview

In a single center, investigator-initiated case series being conducted since November of 2016 to evaluate the safety and effectiveness of our r-SNM System for treatment of patients with FI, performed in Southampton, U.K., 13 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, and 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. 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 the six-month follow-up, as reported by the investigator. This is an investigator-lead case series by an independent physician and while we are providing support to the investigation, the investigator and his team are handling all data collection. Duration of follow up is up to the investigator and is not presently defined.

Safety

There were no unanticipated AEs or serious device-related AEs. No AEs were reported related to recharging our r-SNM System. There were no infections or reports of lead fracture. One out of 10 patients reported pain at implant site which was resolved with resiting of the implant. Additionally, there was one incident of lead migration in a patient who felt pain while dancing but efficacy was restored with new lead placement.

Explants

There were no explants.

Sales and Marketing

We hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. We hired and trained sales representatives and clinical specialists 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 major 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 top 1,000 physicians 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.

In order to support our direct sales team, we have hired 35 clinical support staff. 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.

Our main commercial priority is the United States where we expect to begin to commercialize and market our r-SNM System and generate revenue from product sales. 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, where we have marketing approvals for OAB, FI, and UR, but 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, or CPT, codes, which are created and maintained by the American Medical Association, or 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, or 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 the EU. 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, and approximately $9.1 million for the six months ended June 30, 2019. Our goals include introducing a second generation INS that extends the time between recharging sessions from once every one to two weeks to once a month, incorporating a modified header that allows us to connect our INS to an already implanted InterStim II lead, and over time, expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary cell battery.

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, or 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, or 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, or 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 other 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. In addition, emerging businesses may be in the early stages of developing additional SNM devices or therapies designed to treat OAB or 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. Competitors and other parties may also seek to impact our regulatory approvals through the filing of citizen petitions or other similar documents, which could require costly and time consuming responses to the FDA. Other companies could also launch new or enhanced products and services that we do not offer and that could gain market acceptance quickly. 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 several issued patents and patent applications were licensed from AMF in 2013 pursuant to the License Agreement. As of September 3, 2019, we wholly owned 23 issued U.S. patents and 56 issued foreign patents, and 19 pending U.S. patent applications and 53 pending foreign patent applications. We also license from AMF 27 issued U.S. patents and four pending U.S. patent applications, as well as 58 issued foreign patents and 14 pending foreign patent applications. Issued patents owned or used by us will expire between 2021 and 2039.

Our pending patent applications may not result in issued patents, and we cannot assure you that any current or subsequently issued patents will, individually or collectively, protect our intellectual property rights or provide us with any competitive advantage. We may be required to enforce or defend our intellectual property rights against third parties in the future. See “Risk Factors—Risks Related to Intellectual Property” for additional information regarding these and other risks

related to our intellectual property portfolio and their potential effect on us.

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 us 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 parasympathic control of the heart, lungs and digestive tract and (iii) bladder and bowel 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. We have the right to expand the field of use for the AMF Licensed Products to the 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.

The license is co-exclusive with AMF solely with respect to (i) AMF IP resulting from AMF's performance of any engineering services rendered under the License Agreement, and (ii) AMF's right to use AMF IP for non-commercial research, educational and scholarly purposes.

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. Any and all improvements to AMF IP made by us will be owned by AMF and licensed to us under the License Agreement. As of the date of this prospectus, 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 a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (i) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products and (b) the Minimum Royalty, payable quarterly. The Minimum Royalty will automatically increase each year after 2018, subject to a maximum amount of $200,000 per year. As of June 30, 2019, we have accrued $0.1 million royalties toward the Minimum Royalty. As of December 31, 2018, we accrued $0.1 million toward the Minimum Royalty. 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.

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 bladder and bowel 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 License Agreement allows AMF the right to use the AMF IP for non-commercial research, educational and scholarly purposes.

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

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, or FCC, as well as comparable authorities in the European Economic Area, or EEA. Our r-SNM System is subject to regulation as a medical device under the Federal Food, Drug, and Cosmetic Act, or 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 which therefore are not eligible for 510(k) review but project a low-to-moderate risk may be eligible for the de novo review process.

Our r-SNM System is a Class III device and as such, we obtained PMA approval to market our device for the treatment of FI in the United States and have submitted a PMA application to the FDA for OAB and UR.

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. The PMA is typically supported by data from preclinical studies and human clinical studies. The PMA must also contain a full description of the device and its components, a full description of the methods,

facilities and controls used for manufacturing, and proposed labeling. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with applicable portions of the 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 postmarket 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 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.

Postmarket 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, or UDI, on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database, or 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

- postmarket 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 is 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, or 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, also known as the Medical Devices Directive.

Separately, active implantable medical devices are governed by Directive 90/385/EEC, also known as the Active Implantable Medical Devices Directive, or AIMD Directive. AIMDs are defined as medical devices that rely on a source of electrical energy or any source of power other than that generated by the body, which are totally or partially introduced, either surgically or medically, into the human body and intended to remain after the procedure. Our 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 postmarket 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, or 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;
- postmarket 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, or 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, or 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.

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, or 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, or 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 protected health information, or 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, or 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), or 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, or 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 June 30, 2019, we had 244 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.

Facilities

Our principal office is located at 26 Technology Drive, Irvine, California 92618, where we lease approximately 25,548 square feet of office space. We have also leased approximately 32,621 square feet of additional office space at 15326 Alton Parkway, Irvine, California 92618. We expect to expand our principal offices to include both of these spaces in February 2020. We lease these spaces under a lease that will terminate on or about October 31, 2027.

In addition, we maintain offices at 7575 Irvine Center Drive, Suite 200, Irvine, California 92618, where we lease approximately 12,215 square feet of office space and where we conduct the training of our sales and clinical teams. We lease this space under a lease that terminates on October 31, 2020. We intend to add new facilities as we expand and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

On November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc., which we collectively refer to as the Medtronic Affiliates, filed an initial complaint against us in the United States District Court for the Central District of California, Case No. 8:19-cv-2115. We refer to this matter as the Medtronic Litigation. The complaint asserts that our r-SNM System infringes U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324 and 9,821,112 held by the Medtronic Affiliates, or the Medtronic Patents. The complaint requests customary remedies for patent infringement, including (i) a judgment that we have infringed and are infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) attorneys' fees, (iv) a permanent injunction preventing us from infringing the Medtronic Patents and (v) costs and expenses. We intend to vigorously defend ourselves against these claims. Given the early stage of the Medtronic Litigation, we are unable to predict the likelihood of success of the claims of the Medtronic Affiliates against us or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and require us to dedicate significant financial resources and management resources to our defense. An adverse ruling against us could materially and adversely affect our business, financial position, results of operations or cash flows and could also result in reputational harm. Even if we are successful in defending against these claims, the Medtronic Litigation could result in delays in future product developments, reputational harm or other collateral consequences.

In addition to the Medtronic Litigation, we may be involved in litigation relating to claims arising out of our operations in the normal course of business.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of the rights of our common stock and preferred stock, certain provisions of our amended and restated certificate of incorporation, or certification of incorporation, and our amended and restated bylaws, or bylaws, and applicable law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our certificate of incorporation and bylaws, copies of which are filed as exhibits to the registration statement of which this prospectus forms a part.

General

Our authorized capital stock consists of:

- 50,000,000 shares of common stock, par value $0.0001 per share; and
- 10,000,000 shares of preferred stock, par value $0.0001 per share.

As of June 30, 2019, there were outstanding 28,480,743 shares of our common stock held of record by 474 stockholders, 2,651,778 shares of our common stock issuable upon the exercise of outstanding stock options, and 92,672 shares of our common stock issuable upon the vesting and settlement of restricted stock units.

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 are 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.

Preferred Stock

We have no shares of our preferred stock outstanding, but our board of directors is authorized, without further action by our stockholders, to create and issue one or more series of preferred stock and to fix the rights, powers, preferences and privileges thereof. Among other rights, our board of directors may determine, without further vote or action by our stockholders:

- the number of shares constituting the series and the distinctive designation of the series;
- the dividend rate on the shares of the series, whether dividends will be cumulative, and if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of the series;
- whether the series will have voting rights in addition to the voting rights provided by law and, if so, the terms of the voting rights;
- whether the series will have conversion privileges and, if so, the terms and conditions of conversion;
- whether or not the shares of the series will be redeemable or exchangeable, and, if so, the dates, terms and conditions of redemption or exchange, as the case may be;
- whether the series will have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of the sinking fund; and
- the rights of the shares of the series in the event of our voluntary or involuntary liquidation, dissolution or winding up and the relative rights or priority, if any, of payment of shares of the series.

Any future issuance of shares of preferred stock, or the issuance of rights to purchase shares of preferred stock, could, among other things, decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of the holders of the common stock.

Equity Awards

As of June 30, 2019, options to purchase 2,651,778 shares of common stock were outstanding under the 2014 Plan and the 2018 Plan, of which 630,520 were vested and 1,050,370 were exercisable as of such date. The difference in the amount of vested and exercisable options as of June 30, 2019 represents the rights of certain of our management to exercise their outstanding stock option awards early. In addition, as of June 30, 2019, there were 92,672 shares of common stock issuable upon the vesting and settlement of restricted stock units outstanding under the 2018 Plan.

Registration Rights

We are party to a Fourth Amended and Restated Investors' Rights Agreement, dated March 29, 2018, as amended on October 17, 2018, along with certain holders of our capital stock and certain of our directors (or, in some cases, entities affiliated therewith), or the Rights Agreement.

The Rights Agreement grants the parties thereto certain registration rights in respect of "registrable securities" held by them, which securities include (i) shares of our common stock issued or issuable upon conversion of shares of our preferred stock, (ii) shares of our common stock issued as a dividend or other distribution with respect to the shares in the foregoing clause (i), and (iii) shares of our common stock held by AMF as of the date of the Rights Agreement. The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the Rights Agreement, we generally are required to pay all registration expenses, other than underwriting discounts and commissions, relating to any demand, Form S-3 or piggyback registration by the holders of registrable securities, subject to certain limitations. The Rights Agreement also includes customary indemnification and procedural terms.

Demand Registration Rights

The holders of more than 30% of the registrable securities then outstanding may request that we file a registration statement on Form S-1 registering all or a portion of their registrable securities. Under specified circumstances, we have the right to defer filing of a requested registration statement for a period of not more than 90 days, which right may not be

exercised more than once during any twelve-month period. These registration rights are subject to additional conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances, and our right to decline to effect such registration if the holders requesting holders propose to sell registrable securities at an aggregate price to the public of less than $10.0 million.

Form S-3 Registration Rights

If we are eligible to file a registration statement on Form S-3, the holders of the registrable securities then outstanding have the right to request that we file additional unlimited registration statements for such holders on Form S-3. Under specified circumstances, we have the right to defer filing of a requested registration statement for a period of not more than 90 days, which right may not be exercised more than once during any twelve-month period. These registration rights are subject to additional conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances, and our right to decline to effect such registration if the holders requesting holders propose to sell registrable securities at an aggregate price to the public of less than $1.0 million.

Piggyback Registration Rights

Whenever we propose to file a registration statement, including pursuant to holders' demand registration rights, under the Securities Act, other than with respect to a registration related to employee benefit or similar plans, conversion of debt securities, corporate reorganizations or other transactions under Rule 145 under the Securities Act, or registrations on any forms which do not include substantially the same information regarding us as would be required to be included in a registration statement covering the sale of registrable securities, the holders of registrable securities are entitled to notice of the registration and have the right to request that we include their registrable securities in such registration, subject to certain limitations. We and the underwriters will have the right to limit the number of shares having registration rights to be included in the registration statement.

Expiration of Registration Rights

The registration rights under the Rights Agreement will expire upon the earlier of (i) November 2, 2023 and (ii) with respect to each holder following the closing of our initial public offering, at such time as such holder holds registrable securities constituting less than one percent of our outstanding voting stock if all of such holder's registrable securities may immediately be sold under Rule 144 of the Securities Act during any 90-day period.

Anti-Takeover Effects of Provisions of our Certificate of Incorporation, Bylaws, and Delaware Law

Delaware Anti-Takeover Law

We are subject to Section 203 of the DGCL, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

In general, Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity (other than the corporation and any direct or indirect majority-owned subsidiary of the corporation) or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with, associated with or controlling or controlled by such entity or person.

Certificate of Incorporation and Bylaws

The following provisions of our certificate of incorporation and bylaws may make a change in control of our company more difficult and could delay, defer or prevent a tender offer or other takeover attempt that a stockholder might consider to be in its best interest, including takeover attempts that might result in the payment of a premium to stockholders over the market price for their shares. These provisions also may promote the continuity of our management by making it more difficult for a person to remove or change the incumbent members of our board of directors.

Authorized but Unissued Shares; Undesignated Preferred Stock. The authorized but unissued shares of our common stock will be available for future issuance without stockholder approval, subject to applicable law and the Nasdaq Marketplace Rules. These additional shares may be used for a variety of corporate purposes, including future public offerings to raise additional capital, acquisitions, and employee benefit plans. In addition, our board of directors may authorize, without stockholder approval, the issuance of undesignated preferred stock with voting rights or other rights or preferences designated from time to time by our board of directors (including the right to approve an acquisition or other change in our control). The existence of authorized but unissued shares of common stock or preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

Election and Removal of Directors. The exact number of directors will be fixed from time to time only by a resolution adopted by a majority of the total number of authorized directors, whether or not there exists any vacancies in previously authorized directorships. Our board of directors consists of eight members. Our certificate of incorporation provides that directors may be removed with or without cause and only by the affirmative vote of holders of at least 66 2/3% of our then outstanding voting stock.

Director Vacancies. Our certificate of incorporation authorizes only our board of directors to fill vacant directorships.

No Cumulative Voting. Our certificate of incorporation provides that stockholders do not have the right to cumulate votes in the election of directors (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose).

Special Meetings of Stockholders. Our certificate of incorporation and bylaws provide that special meetings of our stockholders may only be called 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, whether or not there exist any vacancies in previously authorized directorships.

Advance Notice Procedures for Director Nominations. Our bylaws establish advance notice procedures for stockholders seeking to nominate candidates for election as directors at an annual or special meeting of stockholders. Although our bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates to be elected at an annual meeting, our bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Action by Written Consent. Our certificate of incorporation and bylaws provide that any action required or permitted to be taken by the stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by any consent in writing in lieu of a meeting of such stockholders, subject to the rights of the holders of any series of preferred stock.

Amending Our Certificate of Incorporation and Bylaws. Our certificate of incorporation and bylaws may be amended by the affirmative vote of the holders of at least 66 2/3% of the voting power of our then-outstanding capital stock entitled to vote thereon.

Exclusive Jurisdiction. Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of duty by any of our current or former directors or officers, or our stockholders in such capacity, any action asserting a claim arising pursuant to the DGCL, or any action asserting a claim governed by the internal affairs doctrine. In addition, our certificate of incorporation provides that, 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. However, in light of the decision issued by the Court of Chancery in Sciabacucchi v. Salzberg, C.A. No. 2017-0931-JTL, invalidating provisions in the certificates of incorporation of Delaware corporations that purport to limit to federal court the forum in which a stockholder may bring a claim under the Securities Act, we do not currently intend to enforce the foregoing federal forum selection provision unless the *Sciabacucchi* decision is appealed and the Delaware Supreme Court reverses the Chancery Court's decision. If the decision is not appealed or if the Delaware Supreme Court affirms the Chancery Court's decision, then we will seek approval by our stockholders to amend our certificate of incorporation at our next regularly scheduled annual meeting of stockholders to remove the federal forum selection provision.

Conflicts of Interest

Delaware law permits corporations to adopt provisions renouncing any interest or expectancy in certain opportunities that are presented to the corporation or its officers, directors or stockholders. Our certificate of incorporation, to the maximum extent permitted from time to time by Delaware law, renounces any interest or expectancy that we have in, or right to be offered an opportunity to participate in, specified business opportunities that are from time to time presented to our officers, directors or stockholders or their respective affiliates, other than those officers, directors, stockholders or affiliates who are our employees. Our certificate of incorporation provides that, to the fullest extent permitted by law, no director who is not employed by us or his or her affiliates will have any duty to refrain from (i) engaging in a corporate opportunity in the same or similar lines of business in which we or our affiliates now engage or propose to engage or (ii) otherwise competing with us or our affiliates. In addition, to the fullest extent permitted by law, in the event that any non-employee director acquires knowledge of a potential transaction or other business opportunity which may be a corporate opportunity for itself or himself or its or his affiliates or for us or our affiliates, such person will have no duty to communicate or offer such transaction or business opportunity to us or any of our affiliates and they may take any such opportunity for themselves or offer it to another person or entity. Our certificate of incorporation does not renounce our interest in any business opportunity that is expressly offered to a non-employee director solely in his or her capacity as a director of our company. To the fullest extent permitted by law, no business opportunity will be deemed to be a potential corporate opportunity for us unless we would be permitted to undertake the opportunity under our certificate of incorporation, we have sufficient financial resources to undertake the opportunity and the opportunity would be in line with our business.

Nasdaq Global Select Market Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol "AXNX."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

DESCRIPTION OF DEBT SECURITIES

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. While the terms we have summarized below will apply generally to any debt securities that we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in any applicable prospectus supplement or free writing prospectus. The terms of any debt securities offered under any applicable prospectus supplement may differ from the terms described below. Unless the context requires otherwise, whenever we refer to the indenture, we also are referring to any supplemental indentures that specify the terms of a particular series of debt securities.

We will issue the debt securities under the indenture that we will enter into with the trustee named in the indenture. The indenture will be qualified under the Trust Indenture Act of 1939, as amended, or the Trust Indenture Act. We have filed the form of indenture as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

The following summary of material provisions of the debt securities and the indenture is subject to, and qualified in its entirety by reference to, all of the provisions of the indenture applicable to a particular series of debt securities. We urge you to read any applicable prospectus supplements and any related free writing prospectuses related to the debt securities that we may offer under this prospectus, as well as the complete indenture that contains the terms of the debt securities.

General

The indenture does not limit the amount of debt securities that we may issue. It provides that we may issue debt securities up to the principal amount that we may authorize and may be in any currency or currency unit that we may designate. Except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture do not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations, financial condition or transactions involving us.

We may issue the debt securities issued under the indenture as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may be issued with “original issue discount,” or OID, for U.S. federal income tax purposes because of interest payment and other characteristics or terms of the debt securities. One or more series of debt securities may be variable rate debt securities that may be exchanged for fixed rate debt securities. Material U.S. federal income tax considerations applicable to debt securities issued with OID will be described in more detail in any applicable prospectus supplement.

We will comply with Section 14(e) under the Exchange Act to the extent applicable, and any other tender offer rules under the Exchange Act, which may then be applicable, in connection with any obligation we may have to purchase debt securities at the option of the holders thereof. Any such obligation applicable to a series of debt securities will be described in any applicable prospectus supplement.

Any applicable prospectus supplement relating to a series of debt securities being offered will contain the following terms, if applicable:

- the title of the series of debt securities and the ranking;
- the aggregate principal amount and any limit on that amount;
- the price at which the debt securities will be issued;
- the date on which the debt securities mature;
- the fixed or variable rate at which the debt securities will bear interest, or the method by which the rate shall be determined;
- the timing, place and manner of making principal, interest and any premium payments on the debt securities, and, if applicable, where the debt securities may be surrendered for registration of transfer or exchange;
- the date or dates, if any, after which the debt securities may be converted or exchanged into or for our common stock or another company’s securities or property or cash, and the terms of any such conversion or exchange;
- any redemption or early repayment provisions;

- any sinking fund or similar provisions;
- the authorized denominations;
- any applicable subordination provisions;
- any guarantees of the securities by our subsidiaries or others;
- the currency in which we will pay the principal, interest and any premium payments on the debt securities;
- whether the amount of payments of principal of (and premium, if any) or interest, if any, on the debt securities may be determined with reference to an index, formula or other method and the manner in which the amounts shall be determined;
- the denominations in which we will issue the series of debt securities, if other than denominations of $1,000 and any integral multiple thereof;
- the time period within which, the manner in which and the terms and conditions upon which the purchaser of the securities can select the payment currency;
- the provisions, if any, granting special rights to the holders of debt securities upon certain events;
- any additions to or changes in the events of default or covenants with respect to the debt securities, and any change in the right of the trustee or the holders, from those described in this prospectus, to declare principal, premium and interest to be due and payable;
- additions to or changes in or deletions of the provisions relating to covenant defeasance and legal defeasance;
- additions to or changes in the provisions relating to satisfaction and discharge of the indenture;
- additions to or changes in the provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;
- whether and under what circumstances we will pay any additional amounts on the debt securities for any tax, assessment or governmental charge and, if so, whether we will have the option to redeem the debt securities instead of paying those amounts;
- the form (registered and/or bearer securities), any restrictions applicable to the offer, sale or delivery of bearer securities and the terms, if any, upon which bearer securities may be exchanged for registered securities and vice versa;
- the date of any bearer securities or any global security, if other than the date of original issuance of the first security of the series to be issued;
- the person to whom and manner in which any interest shall be payable;
- whether the securities will be issued in whole or in part in the form of one or more global securities;
- the identity of the depositary for global securities;
- whether a temporary security is to be issued with respect to the series and whether any interest payable prior to the issuance of definitive securities of the series will be credited to the account of the persons entitled thereto;
- the terms upon which beneficial interests in a temporary global security may be exchanged in whole or in part for beneficial interests in a definitive global security or for individual definitive securities and the terms upon which exchanges may be made;
- the securities exchange(s), if any, on which the securities will be listed;
- whether any underwriter(s) will act as market maker(s) for the securities;
- the form (certificated or book-entry);
- the form and/or terms of certificates, documents or conditions which may be necessary, if any, for the debt securities to be issuable in final form; and
- additional terms not inconsistent with the provisions of the indenture.

Conversion or Exchange Rights

We will set forth in any applicable prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to settlement upon conversion or exchange and whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Except as set forth in any applicable prospectus supplement, the indenture will provide that we shall not consolidate with, or sell, assign, transfer, lease or convey all or substantially all of our assets to, or merge into, another business entity, unless:

- we are the surviving entity or, in the event that we are not the surviving entity, the entity formed by the transaction (in a consolidation) or the entity which received the transfer of assets is organized under the laws of any state of the United States or the District of Columbia and that the entity assumes all of our obligations under the debt securities and the indenture; and
- immediately after giving effect to the transaction, no event of default, as defined in the indenture, shall have occurred and be continuing.

Notwithstanding the foregoing, we may merge with another business entity or acquire by purchase or otherwise all or any part of the property or assets of any other company in a transaction in which we are the surviving entity.

Events of Default

Unless otherwise specified in any applicable prospectus supplement, the following are events of default with respect to any series of debt securities issued under the indenture:

- failure to pay principal of any debt security of that series when due and payable at maturity, upon acceleration, redemption or otherwise;
- failure to pay any interest on any debt security of that series when due, and the default continues for 30 days;
- failure to make sinking fund payments when due;
- failure to comply with any covenant or warranty contained in the indenture, other than covenants or warranties contained in the indenture solely for the benefit of other series of debt securities, and the default continues for 30 days after notice from the trustee or the holders of at least 25% in principal amount of the then outstanding debt securities of that series;
- certain events of bankruptcy, insolvency or reorganization; and
- any other event of default provided with respect to that particular series of debt securities.

If an event of default occurs and continues, then upon written notice to us, the trustee or the holders of at least 25% in principal amount of the outstanding debt securities of that series may declare the unpaid principal amount of and any accrued and unpaid interest on, all debt securities of that series to be due and payable immediately. However, at any time after a declaration of acceleration with respect to debt securities of any series has been made, the holders of a majority in principal amount of the outstanding debt securities of that series may rescind and annul the acceleration:

- if all events of default other than the nonpayment of principal of or interest on the debt securities of that series which have become due solely because of the acceleration have been waived or cured; and
- the rescission would not conflict with any judgment or decree of a court of competent jurisdiction. For information as to waiver of defaults, see “Modification of Indenture; Waiver” below.

The indenture will provide that, subject to the duty of the trustee during an event of default to act with the required standard of care, the trustee will be under no obligation to exercise any of its rights or powers under the indenture at the request or direction of any of the holders, unless the holders shall have offered to the trustee reasonable security or indemnity. Subject to certain provisions, including those requiring security or indemnification of the trustee, the holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting

any proceeding for any remedy available to the trustee, or exercising any trust or power conferred on the trustee, with respect to the debt securities of that series.

We will be required to furnish to the trustee under the indenture annually a statement as to the performance by us of our obligations under that indenture and as to any default in our performance.

Modification of Indenture; Waiver

Subject to certain exceptions, the terms of the indenture or the debt securities may be amended or supplemented by us and the trustee with the written consent of the holders of at least a majority in principal amount of the outstanding debt securities of each series affected by the amendment with each series voting as a separate class. Without the consent of any holder of the debt securities, we and the trustee may amend the terms of the indenture or the debt securities to:

- cure any ambiguity, defect or inconsistency;
- provide for the assumption of our obligations to holders of the debt securities by a successor corporation;
- provide for uncertificated debt securities in addition to certificated debt securities;
- make any change that does not adversely affect the rights of any holder of the debt securities in any material respect;
- add to, change or eliminate any other provisions of the indenture in respect of one or more series of debt securities if the change would not (i) apply to any security of any series created prior to the execution of a supplemental indenture and entitled to the benefit of the provision, and (ii) modify the rights of the holder of any security or would become effective only when there is no outstanding security of any series created prior to the execution of the supplemental indenture and entitled to the benefits of the provisions proposed to be changed;
- establish any additional series of debt securities; or
- comply with any requirement of the SEC in connection with the qualification of the indenture under the Trust Indenture Act.

However, holders of each series of debt securities affected by a modification must consent to modifications that:

- reduce the principal amount of the debt securities;
- reduce the rate or change the time for payment of interest;
- change the fixed maturity date;
- change the date on which any debt security may be subject to redemption or repurchase, or reduce the redemption or repurchase price;
- make any debt security payable in currency other than that stated in the debt security;
- waive any existing default or event of default and the resulting consequences;
- modify the right of any holder to receive payment of principal or interest on any debt security;
- impair the right of any holder to institute suit for the enforcement of any payment due; or
- make any change in the foregoing amendment provisions which require each holder’s consent.

Any existing default may be waived with the consent of the holders of at least a majority in principal amount of the then outstanding debt securities of the series affected. The consent of the holders of debt securities is not necessary to approve the particular form of any proposed amendment to any indenture. It is sufficient if any consent approves the substance of the proposed amendment.

Covenants

Except as permitted in certain circumstances as discussed under “Consolidation, Merger or Sale,” the indenture will require us to do or cause to be done all things necessary to preserve and keep in full force and effect our existence, rights (declaration and statutory) and franchises; provided, however, that we shall not be required to preserve any right or franchise if we determine that the right or franchise is no longer desirable in the conduct of our business and that the loss of the right or franchise is not disadvantageous in any material respect to the holders of the debt securities.

The indenture will require us to pay or discharge or cause to be paid or discharged, before payment becomes delinquent, all taxes, assessments and governmental charges levied or imposed upon us, except any tax, assessment, charge or claim the amount or applicability of which is being contested in good faith.

Reference is made to the indenture and any applicable prospectus supplement for information with respect to any additional covenants specific to a particular series of debt securities.

Discharge

Except as otherwise set forth in any applicable prospectus supplement, we may terminate our obligations under the debt securities of any series, and the corresponding obligations under the indenture when:

- we have paid or deposited with the trustee funds or United States government obligations in an amount sufficient to pay at maturity all outstanding debt securities of the series, including interest other than destroyed, lost or stolen debt securities of the series which have not been replaced or paid;
- all outstanding debt securities of the series have been delivered (other than destroyed, lost or stolen debt securities of the series which have not been replaced or paid) to the trustee for cancellation;
- all outstanding debt securities of any series have become due and payable; or
- we have paid all other sums payable under the indenture.

In addition, we will have the option to terminate substantially all our obligations under the debt securities of any series and the corresponding obligations under the indenture, and we may exercise that option if:

- we have paid or deposited with the trustee, in trust an amount of cash or United States government obligations sufficient to pay all outstanding principal of and interest on the then outstanding debt securities of the series at maturity or upon their redemption, as the case may be;
- the deposit will not result in a breach of, or constitute a default under, the indenture;
- no default or event of default shall have occurred and continue on the date of deposit and no event of default as a result of a bankruptcy or event which with the giving of notice or the lapse of time would become a bankruptcy event of default shall have occurred and be continuing on the 91st day after that date;
- we deliver to the trustee a legal opinion that we have received from, or there has been published by, the United States Internal Revenue Service a ruling, or there has been a change in tax law, in either case to the effect that the holders of the debt securities of the series will not recognize income, gain or loss for Federal income tax purposes as a result of our exercise of our option and shall be subject to Federal income tax on the same amounts and in the same manner and at the same times as would have been the case if we did not exercise our option; or
- certain other conditions are met.

We will have the option to be released from our obligations with respect to the covenants to deliver reports required to be filed with the SEC and an annual compliance certificate, and to make timely payments of taxes (including covenants described in an applicable prospectus supplement), and any event of default occurring because of a default with respect to the covenants as they related to any series of debt securities, and we may exercise that option if:

- we deposit or cause to be deposited with the trustee in trust an amount of cash or United States government obligations sufficient to pay and discharge when due the entire unpaid principal of and interest on all outstanding debt securities of any series;
- the deposit will not result in a breach of, or constitute a default under, the indenture;
- no default or event of default shall have occurred and be continuing on the date of deposit and no event of default as a result of a bankruptcy or event which with the giving of notice or the lapse of time would become a bankruptcy event of default shall have occurred and be continuing on the 91st day after that date;
- we deliver to the trustee a legal opinion that the holders of the debt securities of the series will not recognize income, gain or loss for Federal income tax purposes as a result of our exercise of our option and shall be subject to Federal income tax on the same amounts and in the same manner and at the same times as would have been the case if we did not exercise our option; and
- certain other conditions are met.

Upon satisfaction of the applicable conditions, our obligations under the indenture with respect to the debt securities of the series, other than with respect to the covenants and events of default referred to above, shall remain in full force and effect.

Notwithstanding the foregoing, no discharge or defeasance described above shall affect the following obligations to or rights of the holders of any series of debt securities:

- rights of registration of transfer and exchange of debt securities of the series;
- rights of substitution of mutilated, defaced, destroyed, lost or stolen debt securities of the series;
- rights of holders of debt securities of the series to receive payments of principal thereof and premium, if any, and interest thereon when due;
- rights, obligations, duties and immunities of the trustee;
- rights of holders of debt securities of the series as beneficiaries with respect to property deposited with the trustee and payable to all or any of them; and
- our obligations to maintain an office or agency in respect of the debt securities of the series.

Form, Exchange and Transfer

We expect payment of principal, premium, if any, and any interest on the debt securities to be payable, and the exchange and the transfer of debt securities will be registrable, at the office of the trustee or at any other office or agency we maintain for that purpose. We expect to issue debt securities in denominations of U.S. $1,000 or integral multiples of $1,000. No service charge will be made for any registration of transfer or exchange of the debt securities, but we may require a payment to cover any tax or other governmental charges payable in connection with an exchange or transfer.

A holder of debt securities may transfer or exchange those debt securities in accordance with the indenture. The registrar for the debt securities may require a holder, among other things, to furnish appropriate endorsements and transfer documents, and to pay any taxes and fees required by law or permitted by the indenture. The registrar is not required to transfer or exchange any debt security selected for redemption or any debt security for a period of 15 days before a selection of debt security to be redeemed. The registered holder of a debt security may be treated as the owner of the security for all purposes.

We will name in any applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

Replacement Securities

Any mutilated certificate representing a debt security or a certificate representing a debt security with a mutilated coupon will be replaced by us at the expense of the holder upon surrender of the certificate to the trustee. Certificates representing debt securities or coupons that become destroyed, stolen or lost will be replaced by us at the expense of the holder upon delivery to us and the trustee of evidence of any destruction, loss or theft satisfactory to us and the trustee, provided that neither we nor the trustee has been notified that the certificate or coupon has been acquired by a bona fide purchaser. In the case of any coupon which becomes destroyed, stolen or lost, the coupon will be replaced by issuance of a new certificate representing the debt security in exchange for the certificate representing the debt security to which the coupon appertains. In the case of a destroyed, lost or stolen certificate representing the debt security or coupon, an indemnity bond satisfactory to the trustee and us may be required at the expense of the holder of the debt security before a replacement certificate will be issued.

Information Concerning the Trustee

We will identify in any applicable prospectus supplement relating to any series of debt securities the trustee with respect to the series. The indenture and the Trust Indenture Act contain certain limitations on the rights of the trustee, should it become our creditor, to obtain payment of claims in certain cases, or to realize on certain property received in respect of any the claim, as security or otherwise. The trustee and its affiliates may engage in, and will be permitted to continue to engage in, other transactions with us and our affiliates, but if the trustee acquires any conflicting interest, as defined in the Trust Indenture Act, it must eliminate the conflict or resign.

The holders of a majority in principal amount of the then outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for exercising any remedy available to the trustee. The Trust Indenture Act and the indenture provide that in case an event of default occurs is continuing, the trustee will be required, in the exercise of its rights and powers, to use the degree of care and skill of a prudent man in the conduct of his own affairs. Subject to those provisions, the trustee will be under no obligation to exercise any of its rights or powers under the indenture at the request of any of the holders of the debt securities, unless they have offered to the trustee indemnity satisfactory to it.

Global Debt Securities

Unless we indicate otherwise in any applicable prospectus supplement, the following provisions will apply to all debt securities.

The debt securities of a series may be issued in whole or in part in the form of one or more global securities that will be deposited with a depositary that we will identify in any applicable prospectus supplement. Each global security will be deposited with the depositary and will bear a legend regarding any related restrictions or other matters as may be provided for pursuant to the applicable indenture.

Unless any applicable prospectus supplement states otherwise, no global security may be transferred to, or registered or exchanged for, debt securities registered in the name of, any person or entity other than the depositary, unless:

- the depositary has notified us that it is unwilling or unable or is no longer qualified to continue as depositary;
- we order the trustee that the global security shall be so transferable, registrable and exchangeable, and the transfers shall be registrable; or
- other circumstances, if any, as may be described in any applicable prospectus supplement.

All debt securities issued in exchange for a global security or any portion of a global security will be registered in those names as the depositary may direct. The specific terms of the depositary arrangement with respect to any portion of a series of debt securities to be represented by a global security will be described in any applicable prospectus supplement.

Debt securities which are to be represented by a global security to be deposited with or on behalf of a depositary will be represented by a global security registered in the name of the depositary or its nominee. Upon the issuance of the global security, and the deposit of the global security with the depositary, the depositary will credit, on its book-entry registration and transfer system, the respective principal amounts of the debt securities represented by the global security to the accounts of institutions that have accounts with the depositary or its nominee, or the Participants. The accounts to be credited will be designated by the underwriters or agents of the debt securities or by us, if the debt securities are offered and sold directly by us.

Ownership of beneficial interests in a global security will be limited to Participants or persons that may hold interests through Participants. Ownership of beneficial interests in a global security will be shown on, and the transfer of that ownership interest will be effected only through, records maintained by the depositary or its nominee for the global security or by Participants or persons that hold through Participants.

The laws of some jurisdictions require that certain purchasers of securities take physical delivery of the securities in certificated form. Those laws may impair the ability to transfer beneficial interests in global securities.

So long as the depositary, or its nominee, is the registered owner of a global security, the depositary or the nominee, as the case may be, will be considered the sole owner or holder of the debt securities represented by the global security for all purposes under the indenture. Payment of principal of, and premium and interest, if any, on debt securities will be made to the depositary or its nominee as the registered owner or bearer as the case may be of the global security representing the debt securities. Each person owning a beneficial interest in a global security must rely on the procedures of the depositary and, if the person is not a Participant, on the procedures of the Participant through which the person owns its interest, to exercise any rights of a holder under the indenture. If we request any action of holders or if an owner of a beneficial interest in a global security desires to give any notice or take any action a holder is entitled to give or take under the indenture, the depositary will authorize the Participants to give the notice or take the action, and Participants would authorize beneficial owners owning through the Participants to give the notice or take the action or would otherwise act upon the instructions of beneficial owners owning through them.

The rights of any holder of a debt security to receive payment of principal and premium of, if any, and interest, on or after the respective due dates expressed or provided for in the debt security, or to institute suit for the enforcement of any payment on or after the applicable date, shall not be impaired or affected without the consent of the holders.

Neither we, the trustee, any paying agent nor the security registrar for a debt security will have any responsibility or liability for any aspect of the records relating to or payments made on account of beneficial ownership interests of the global security for the debt security or for maintaining, supervising or receiving any records relating to the beneficial ownership interests.

We expect that the depositary or its nominee, upon receipt of any payment of principal, premium or interest, will credit immediately Participants' accounts with payments in amounts proportionate to their respective beneficial interests in the principal amount of the global security as shown on the records of the depositary or its nominee. We also expect that payments by Participants to owners of beneficial interests in a global security held through the Participants will be governed by standing instructions and customary practices, as is now the case with securities held for the accounts of customers in bearer form or registered in "street name," and will be the responsibility of the Participants.

If the depositary for a global security representing debt securities of a particular series is at any time unwilling or unable to continue as depositary and we do not appoint a successor depositary within 90 days, we will issue debt securities of the series in definitive form in exchange for the global security. In addition, we may at any time and in our sole discretion determine not to have the debt securities of a particular series represented by one or more global securities and, in that event, will issue debt securities of the series in definitive form in exchange for all of the global securities representing debt securities of the series.

Payment and Paying Agents

Unless we otherwise indicate in any applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in any applicable prospectus supplement, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in any applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indenture and the debt securities will be governed by and construed in accordance with the internal laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

DESCRIPTION OF WARRANTS

We may issue warrants for the purchase of shares of our common stock or preferred stock or of debt securities in one or more series. We may issue warrants independently or together with other securities, and the warrants may be attached to or separate from any offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and the investors or a warrant agent. The following summary of material provisions of the warrants and warrant agreements is subject to, and qualified in its entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to a particular series of warrants. The terms of any warrants offered under a prospectus supplement may differ from the terms described below. We urge you to read the applicable prospectus supplement and any related free writing prospectus, as well as the complete warrant agreements and warrant certificates that contain the terms of the warrants.

General

Any applicable prospectus supplement will describe the specific terms of any warrants that we issue or offer, including:

- the title of the warrants;
- the aggregate number of warrants;
- the price or prices at which the warrants will be issued;
- the currencies in which the price or prices of the warrants may be payable;
- the designation, amount and terms of our capital stock or debt securities purchasable upon exercise of the warrants;
- the designation and terms of our other securities, if any, that may be issued in connection with the warrants, and the number of warrants issued with each corresponding security;
- if applicable, the date that the warrants and the securities purchasable upon exercise of the warrants will be separately transferable;
- the prices and currencies for which the securities purchasable upon exercise of the warrants may be purchased;
- the date that the warrants may first be exercised;
- the date that the warrants expire;
- the minimum or maximum amount of warrants that may be exercised at any one time;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- information with respect to book-entry procedures, if any;
- the manner in which the warrant agreements and warrants may be modified;
- a discussion of certain federal income tax considerations; and
- any other material terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Exercise of Warrants

Each warrant will entitle the holder to purchase for cash the principal amount of common stock, preferred stock or debt securities at the applicable exercise price set forth in, or determined as described in, any applicable prospectus supplement. Warrants may be exercised at any time up to the close of business on the expiration date set forth in any applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Warrants may be exercised by delivering to the corporation trust office of the warrant agent or any other officer indicated in the applicable prospectus supplement (a) the warrant certificate properly completed and duly executed and (b)

payment of the amount due upon exercise. As soon as practicable following exercise, we will forward the common stock, preferred stock or debt securities purchasable upon exercise. If less than all of the warrants represented by a warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants if the expiration date of the warrants has not occurred. If we so indicate in any applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Governing Law

Unless we provide otherwise in any applicable prospectus supplement, the warrants and warrant agreements, and any claim, controversy or dispute arising under or related to the warrants or warrant agreements, will be governed by and construed in accordance with the laws of the State of New York.

Enforceability of Rights by Holders of Warrants

Each warrant agent, if any, will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

Outstanding Warrants

As of June 30, 2019, there were 40,000 shares of our common stock issuable upon the exercise of outstanding warrants.

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in any applicable prospectus supplement and any related free writing prospectus. The terms of any units offered under an applicable prospectus supplement may differ from the terms described below. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of unit agreement that describes the terms of the series of units we are offering, and any supplemental agreements, before the issuance of the related series of units. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we sell under this prospectus, as well as the complete unit agreement and any supplemental agreements that contain the terms of the units.

DESCRIPTION OF UNITS

General

We may issue units comprised of one or more debt securities, common stock, preferred stock, warrants and/or rights in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We will describe in any applicable prospectus supplement the terms of the series of units, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those described under “Description of Capital Stock,” “Description of Debt Securities,” “Description of Warrants,” and “Description of Rights” will apply to each unit and to any common stock, preferred stock, debt security, warrant or right included in each unit, respectively.

Issuance in Series

We may issue units in the amounts and in numerous distinct series as we determine.

Enforceability of Rights by Holders of Units

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

Title

We, the unit agent and any of their agents may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purposes and as the person entitled to exercise the rights attaching to the units, despite any notice to the contrary.

DESCRIPTION OF RIGHTS

We may issue rights to purchase shares of our common stock, preferred stock, or warrants in one or more series. Rights may be issued independently or together with any other offered security and may or may not be transferable by the person purchasing or receiving the subscription rights. In connection with any rights offering to our stockholders, we may enter into a standby underwriting arrangement with one or more underwriters pursuant to which the underwriters will purchase any of the offered securities remaining unsubscribed after the expiration of the rights offering. In connection with a rights offering to our stockholders, we will distribute certificates evidencing the rights and an applicable prospectus supplement to our stockholders on the record date that we set for receiving rights in the rights offering.

An applicable prospectus supplement will describe the following terms of rights in respect of which this prospectus is being delivered:

- the title of the rights;
- the securities for which the rights are exercisable;
- the exercise price for the rights;
- the currencies in which the price or prices of the rights may be payable;
- the date of determining the security holders entitled to the rights distribution;
- the number of the rights issued to each security holder;
- the extent to which the rights are transferable;
- if applicable, a discussion of the material United States federal income tax considerations applicable to the issuance or exercise of the rights;
- the date on which the right to exercise the rights shall commence, and the date on which the rights shall expire (subject to any extension);
- the conditions to completion of the rights offering;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the rights;
- the extent to which the rights include an over-subscription privilege with respect to unsubscribed securities;
- if applicable, the material terms of any standby underwriting or other purchase arrangement that we may enter into in connection with the rights offering; and
- any other terms of the rights, including terms, procedures and limitations relating to the exchange and exercise of the rights.

Each right will entitle the holder to purchase for cash the amount of securities, at the exercise price. Rights may be exercised at any time up to the close of business on the expiration date of the rights. After the close of business on the expiration date, all unexercised rights will become void. The manner in which rights may be exercised will be described in any applicable prospectus supplement. Upon receipt of payment and the proper completion and due execution of the rights certificate at the designated office of the rights agent or any other office indicated in any applicable prospectus supplement, we or the transfer agent will forward, as soon as practicable, the securities purchased through upon the exercise of the rights. We may determine to offer any unsubscribed offered securities directly to persons other than stockholders, to or through agents, underwriters or dealers or through a combination of the methods, including pursuant to standby underwriting arrangements, as set forth in any applicable prospectus supplement.

SELLING STOCKHOLDERS

This prospectus relates to the sale or other disposition of up to an aggregate of 9,061,028 shares of our common stock previously issued to the selling stockholders.

The table below sets forth, to our knowledge, information as of the date of this prospectus for the selling stockholders and other information regarding the beneficial ownership of the shares of common stock held by the selling stockholders. The second column lists the number of shares and percentage of common stock beneficially owned by the selling stockholders as of November 5, 2019. The third column lists the maximum number of shares of common stock that may be sold or otherwise disposed of by the selling stockholders pursuant to the registration statement of which this prospectus forms a part. The fourth column lists the number of shares and percentage of common stock beneficially owned by the selling stockholders upon completion of the offering contemplated hereby, assuming the sale of all shares of common stock that may be sold or otherwise disposed of by the selling stockholders pursuant to the registration statement of which this prospectus forms a part. The selling stockholders may sell or otherwise dispose of some, all or none of their shares.

Pursuant to the rules and regulations of the SEC, beneficial ownership includes any shares of common stock as to which a selling stockholder has sole or shared voting power or investment power and any shares of common stock that the selling stockholder has the right to acquire within 60 days of November 5, 2019. The percent of beneficial ownership for each selling stockholder is based on 28,602,766 shares of our common stock outstanding as of November 5, 2019. The selling stockholders have contractual rights to require us to file the registration statement of which this prospectus is a part, as described under "Description of Capital Stock-Registration Rights."

The shares of common stock being covered hereby may be sold or otherwise disposed of from time to time during the period the registration statement of which this prospectus is a part remains effective, by or for the account of the selling stockholders. After the date of effectiveness, the selling stockholders may have sold or transferred, in transactions covered by this prospectus or in transactions exempt from the registration requirements of the Securities Act, some or all of their common stock. See the section entitled "Plan of Distribution" elsewhere in this prospectus.

Information about the selling stockholders may change over time. Any changed information will be set forth in an amendment to the registration statement or supplement to this prospectus, to the extent required by law.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Axonics Modulation Technologies, Inc., 26 Technology Drive, Irvine, California 92618.

	Shares of Common Stock Beneficially Owned Prior to Offering		Number of Shares of Common Stock Being Offered[1]	Shares of Common Stock Beneficially Owned Upon Completion of this Offering[1]	
Name of Selling Stockholder	**Number**	**Percentage**		**Number**	**Percentage**
BioDiscovery 4 FCPR[2]	2,690,795	9.4%	2,690,795	-	-
Longitude Venture Partners III, L.P.[3]	2,933,333	10.3%	2,933,333	-	-
Advent Life Sciences Fund II LP[4]	1,694,349	5.9%	1,694,349	-	-
NeoMed Innovation V L.P.[5]	1,520,884	5.3%	1,520,884	-	-
N5 Investments AS[6]	86,667	*	86,667	-	-
Raymond W. Cohen[7]	860,151	3.0%	75,000	785,151	2.7%
Dan L. Dearen[8]	453,473	1.6%	60,000	393,473	1.4%

* Less than 1%

(1) Assumes that each of the selling stockholders will sell all shares of common stock registered under this prospectus directly held by it.

(2) Andera Partners is the manager of BioDiscovery 4 FCPR and has voting and dispositive power over the shares held by BioDiscovery 4 FCPR. Raphaël Wisniewski, who is a member of our board of directors, is a partner of Andera Partners, and may be deemed to have voting and dispositive power over the shares held by BioDiscovery 4 FCPR. Mr. Wisniewski disclaims beneficial ownership of such shares. The mailing address of BioDiscovery 4 FCPR is 347 Rue Saint St Honoré, 75001 Paris Cedex 08 France.

(3) Longitude Capital Partners III, LLC is the General Partner of Longitude Venture Partners III, L.P. and may be deemed to share voting and investment power over the shares held by Longitude Venture Partners III, L.P. Juliet Tammenoms Bakker, who is a member of our board of directors, and Patrick G. Enright are managing members of Longitude Capital Partners III, LLC, and may be deemed to share voting and investment power over the shares held by Longitude Venture Partners III, L.P. Each of these individuals disclaims beneficial ownership of such shares, except to the extent of his or her pecuniary interest therein. The mailing address of Longitude Venture Partners III, L.P. is 2740 Sand Hill Road, 2nd Floor, Menlo Park, California 94025.

(4) Consists of (i) 58,234 shares of common stock held by Advent Life Sciences LLP and (ii) 1,636,115 shares of common stock held by Advent Life Sciences Fund II LLP. Advent Life Sciences LLP is the general partner of Advent Life Sciences Fund II LLP and has voting and dispositive power over the shares held by Advent Life Sciences Fund II LLP. Dr. Shahzad Malik is a general partner of Advent Life Sciences LLP, and may be deemed to have voting and dispositive power over the shares held by Advent Life Sciences LLP. The mailing address of Advent Life Sciences LLP and Advent Life Sciences Fund II LLP is 158-160 North Gower Street, London, United Kingdom NWI 2ND.

(5) NeoMed Innovation V Limited is the general partner of NeoMed Innovation V L.P. and has voting and dispositive power over the shares held by NeoMed Innovation V L.P. Erik Amble, who is a member of our board of directors, is a director of NeoMed Innovation V Limited, and may be deemed to have voting and dispositive power over the shares held by NeoMed Innovation V L.P. Mr. Amble disclaims beneficial ownership of such shares. Mr. Amble and certain of his family members own all of the share capital of AS Fansea, which is a minority stockholder of NeoMed Innovation V L.P. The mailing address of NeoMed Innovation V L.P. is 13 Castle Street, St. Helier, Y9 JE4 5UT.

(6) Carl Christian Gilhuus-Moe is the chairman of N5 Investments AS and may be deemed to have voting and dispositive power over the shares held by N5 Investments AS. Mr. Gilhuus-Moe disclaims beneficial ownership of such shares. The mailing address of N5 Investments AS is Parkveien 55, N-0256 Oslo, Norway.

(7) Consists of (i) 683,391 shares of common stock held by Mr. Cohen, (ii) 168,000 shares of common stock underlying stock options exercisable within 60 days of November 5, 2019, and (iii) 8,760 shares of common stock held by the Cielo Trust established March 30, 2018. Mr. Cohen is a trustee of the Cielo Trust established March 30, 2018, and as a result, shares voting and dispositive power over the shares held by it.

(8) Consists of (i) 138,491 shares of common stock held by Mr. Dearen, and (ii) 314,982 shares of common stock underlying stock options exercisable within 60 days of November 5, 2019.

Relationship with Selling Stockholders

Mr. Wisniewski, Ms. Tammenoms Bakker and Mr. Amble are members of our board of directors.

Please see our Annual Report on Form 10-K, “Item 13—Certain Relationships and Related Transactions, and Director Independence,” which is incorporated by reference in this prospectus, for more information regarding our relationships with certain Selling Stockholders.

PLAN OF DISTRIBUTION

We or the selling stockholders may sell the securities offered by this prospectus in any one or more of the following ways from time to time:

- through agents;
- to or through underwriters;
- to or through brokers or dealers;
- directly to investors, including through a specific bidding, auction or other process;
- directly to agents;
- through a combination of any such methods of sale; or
- by any other method permitted pursuant to applicable law.

The distribution of securities may be effected from time to time in one or more transactions, including block transactions and transactions on the Nasdaq Global Market or any other organized market where the shares may be traded. The securities may be sold at a fixed price or prices, which may be changed, or at market prices prevailing at the time of sale, at prices relating to the prevailing market prices or at negotiated prices. The consideration may be cash or another form negotiated by the parties. Agents, underwriters or broker-dealers may be paid compensation for offering and selling the securities. That compensation may be in the form of discounts, concessions or commissions to be received from us or the selling stockholders, or from the purchasers of the securities. Selling stockholders, dealers and agents participating in the distribution of the securities may be deemed to be underwriters, and compensation received by them on resale of the securities may be deemed to be underwriting discounts.

Agents may from time to time solicit offers to purchase the securities. If required, any agent involved in the offer or sale of the securities will be named, and any compensation payable to the agent will be described, in the applicable prospectus supplement. Unless otherwise indicated in the prospectus supplement, any agent will be acting on a best efforts basis for the period of its appointment. Any agent selling the securities covered by this prospectus may be deemed to be an underwriter, as that term is defined in the Securities Act, of the securities.

If underwriters are used in a sale, securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale, or under delayed delivery contracts or other contractual commitments. Securities may be offered to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. If an underwriter or underwriters are used in the sale of securities, an underwriting agreement will be executed with the underwriter or underwriters at the time an agreement for the sale is reached. The underwriter may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for which they may act as agent. The applicable prospectus supplement will set forth the managing underwriter or underwriters, as well as any other underwriter or underwriters, with respect to a particular underwritten offering of securities, and will set forth the terms of the transactions, including compensation of the underwriters and dealers and the public offering price, if applicable. Unless otherwise indicated in a prospectus supplement, an agent will be acting on a best efforts basis and a dealer will purchase securities as a principal, and may then resell the securities at varying prices to be determined by the dealer. The prospectus and prospectus supplement will be used by the underwriters to resell the securities.

If a dealer is used in the sale of the securities, we, the selling stockholders or an underwriter will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. To the extent required, the name of the dealer and the terms of the transactions will be set forth in the prospectus supplement.

We may directly solicit offers to purchase the securities and we or the selling stockholders may make sales of securities directly to institutional investors or others. These persons may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale of the securities. To the extent required, the prospectus supplement will describe the terms of any such sales, including the terms of any bidding or auction process, if used.

Agents, underwriters and dealers may be entitled under agreements which may be entered into with us or the selling stockholders to indemnification by us or the selling stockholders against specified liabilities, including liabilities incurred under

the Securities Act, or to contribution by us or the selling stockholders to payments it may be required to make in respect of such liabilities. The prospectus supplement will describe the terms and conditions of such indemnification or contribution. Some of the agents, underwriters or dealers, or their affiliates may be customers of, engage in transactions with or perform services for us or our subsidiaries in the ordinary course of business.

Under the securities laws of some states, the securities offered by this prospectus may be sold in those states only through registered or licensed brokers or dealers.

We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. If such shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. In addition to the above-mentioned methods of sale, the selling stockholders may also resell all or a portion of their securities in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(a)(1) under the Securities Act, if available, rather than under this prospectus or an applicable prospectus supplement, provided that the selling stockholders meet the criteria and conform to the requirements of those provisions.

In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and if such short sale shall take place after the date that the registration statement of which this prospectus is a part is declared effective by the Commission, the selling stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered on the registration statement of which this prospectus forms a part to cover short sales of our common stock made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the Commission.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if any such selling stockholder defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus, or an amendment or supplement thereto, under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

Because selling stockholders may be deemed to be "underwriters" within the meaning of Section 2(a)(11) of the Securities Act, the selling stockholders may be subject to the prospectus delivery requirements of the Securities Act, which may include delivery through the facilities of the Nasdaq Global Market pursuant to Rule 153 under the Securities Act.

Any person participating in the distribution of common stock registered under the registration statement that includes this prospectus will be subject to applicable provisions of the Exchange Act and the applicable SEC rules and regulations, including, among others, Regulation M, which may limit the timing of purchases and sales of any of common stock by any such person. Furthermore, Regulation M may restrict the ability of any person engaged in the distribution of common stock to engage in market-making activities with respect to common stock. These restrictions may affect the marketability of common stock and the ability of any person or entity to engage in market-making activities with respect to common stock.

Certain persons participating in the offering may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act that stabilize, maintain or otherwise affect the price of the offered securities. For a description of these activities, see the information under the heading "Underwriting" in the applicable prospectus supplement.

We may engage in at-the-market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in

connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

LEGAL MATTERS

The validity of the securities offered by this prospectus and any applicable prospectus supplement thereto will be passed upon for us by K&L Gates LLP, Irvine, California. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we name in the applicable prospectus supplement.

EXPERTS

The consolidated financial statements as of and for the years ended December 31, 2018 and 2017 incorporated by reference in this prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus and any accompanying prospectus supplement do not contain all of the information set forth in the registration statement and its exhibits and schedules in accordance with SEC rules and regulations. For further information with respect to us and the securities being offered hereby, you should read the registration statement, including its exhibits and schedules. Statements contained in this prospectus and any accompanying prospectus supplement, including documents that we have incorporated by reference, as to the contents of any contract or other document referred to are not necessarily complete, and, with respect to any contract or other document filed as an exhibit to the registration statement or any other such document, each such statement is qualified in all respects by reference to the corresponding exhibit. You should review the complete document to evaluate these statements. You may obtain copies of the registration statement and its exhibits via the SEC's EDGAR database or our website.

We file annual, quarterly and current reports, proxy statements and other documents with the SEC under the Exchange Act. The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers, including our company, that file electronically with the SEC. You may obtain documents that we file with the SEC at http://www.sec.gov.

We also make these documents available on our website at www. axonicsmodulation.com. Our website and the information contained or connected to our website is not incorporated by reference in this prospectus or any accompanying prospectus supplement, and you should not consider it part of this prospectus or any accompanying prospectus supplement. You may also request a copy of these filings, at no cost, by writing us at 26 Technology Drive, Irvine, CA 92618, Attention: General Counsel or telephoning us at (949) 396-6322.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" in this prospectus certain of the information we file with the SEC. This means we can disclose important information to you by referring you to another document that has been filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the SEC will automatically update and supersede information contained in this prospectus and any accompanying prospectus supplement. We incorporate by reference the documents listed below that we have previously filed with the SEC:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 5, 2019, as amended by our Annual Report on Form 10-K/A for the year ended December 31, 2018, as filed with the SEC on April 30, 2019;
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 from our Definitive Proxy Statement on Schedule 14A (other than information furnished rather than filed) filed with the SEC on July 9, 2019;
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2019 as filed with the SEC on May 8, 2019; and for the quarter ended June 30, 2019, as filed with the SEC on August 5, 2019;
- our Current Reports on Form 8-K (other than information furnished rather than filed) filed with the SEC on March 5, 2019, April 12, 2019, June 11, 2019, July 12, 2019, August 22, 2019, September 9, 2019 and November 6, 2019; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed with SEC on October 25, 2018, including any amendment or report filed for the purpose of updating such description.

We also incorporate by reference into this prospectus additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the completion or termination of the offering of the securities described in this prospectus, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information deemed furnished and not filed with the SEC. Any statements contained in a previously filed document incorporated by reference into this prospectus is deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have "furnished" to the SEC pursuant to the Exchange Act shall be incorporated by reference into this prospectus.

We will furnish without charge to each person, including any beneficial owner, to whom a prospectus is delivered, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Axonics Modulation Technologies, Inc., 26 Technology Drive, Irvine, CA 92618, Attention: General Counsel or telephoning us at (949) 396-6322. You may also access the documents incorporated by reference in this prospectus through our website at www.axonicsmodulation.com. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

$110,000,000

Axonics Modulation Technologies, Inc.

Common Stock

PROSPECTUSSUPPLEMENT

BofA Securities

Barclays

Wells Fargo Securities

November , 2019