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As filed with the Securities and Exchange Commission on October 25, 2018.

Registration No. 333-227732

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Amendment No. 2
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Axonics Modulation Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**45-4744083**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

26 Technology Drive
Irvine, California 92618
(949) 396-6322
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Raymond W. Cohen
Chief Executive Officer
Axonics Modulation Technologies, Inc.
26 Technology Drive
Irvine, California 92618
(949) 396-6322
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Michael A. Hedge	**Michael V. Williamson**	**Ilir Mujalovic**
K&L Gates LLP	**Senior Vice President and General Counsel**	**Shearman & Sterling LLP**
1 Park Plaza	**Axonics Modulation Technologies, Inc.**	**599 Lexington Avenue**
Twelfth Floor	**26 Technology Drive**	**New York, New York 10022**
Irvine, California 92614	**Irvine, California 92618**	**(212) 848-4000**
(949) 253-0900	**(949) 396-6322**	

Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee(3)
Common Stock, $0.0001 par value per share	7,667,050	$16.00	$122,672,800	$14,868

(1) Includes 1,000,050 shares that the underwriters have the option to purchase.
(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(a) of the Securities Act of 1933, as amended.
(3) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said Section 8(a), may determine.

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EXPLANATORY NOTE

Axonics Modulation Technologies, Inc. is filing this Amendment No. 2 (the "Amendment") to its Registration Statement on Form S-1 (File No. 333-227732) (the "Registration Statement"), solely to clarify who is signing as Principal Accounting Officer on the signature page of the Registration Statement. Accordingly, no change is made in this Amendment to the preliminary prospectus constituting Part 1 of the Registration Statement (other than to update the date thereof) or Items 13, 14, 15, 16 (other than to identify that certain exhibits were previously filed) or 17 of Part II of the Registration Statement.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus 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
Preliminary Prospectus dated October 25, 2018

PROSPECTUS

6,667,000 Shares

Axonics Modulation Technologies, Inc.

Common Stock

This is Axonics Modulation Technologies, Inc.'s initial public offering. We are selling 6,667,000 shares of our common stock.

We expect the public offering price to be between $14.00 and $16.00 per share. Currently, no public market exists for the shares. After pricing of the offering, we expect that the shares will trade on the Nasdaq Global Market under the symbol "AXNX."

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

Investing in our common stock involves risks that are described in the "Risk Factors" section beginning on page 17 of this prospectus.

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

(1) We refer you to "Underwriting" beginning on page 208 for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 1,000,050 shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

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.

Certain of our existing stockholders that are affiliated with certain of our directors have indicated an interest in purchasing an aggregate of up to approximately $45.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

The shares will be ready for delivery on or about , 2018.

BofA Merrill Lynch **Morgan Stanley**

Wells Fargo Securities **SunTrust Robinson Humphrey**

The date of this prospectus is , 2018.

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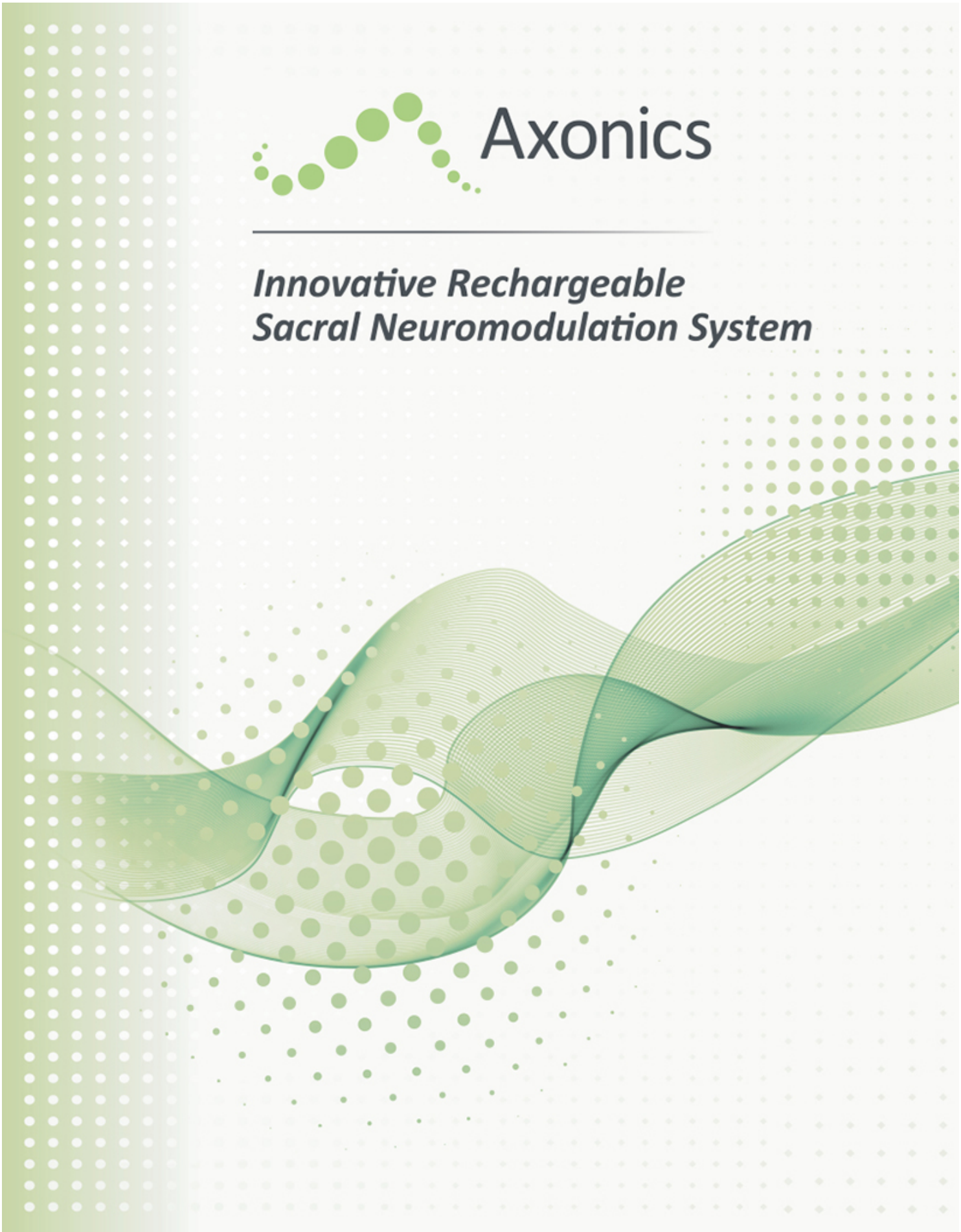

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus 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 or in any applicable free writing prospectus is current only as of its date, 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 that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this 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 must inform themselves, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

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.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider in making your investment decision. Before deciding to invest in shares of our common stock, you should read the entire prospectus carefully, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the consolidated financial statements and the related notes appearing at the end of this prospectus. Unless the context requires otherwise, references in this prospectus to "Axonics," "our company," "we," "us" and "our" refer to Axonics Modulation Technologies, Inc. and our consolidated subsidiaries.

Overview

We are a medical technology company focused on the design, development, and commercialization of innovative and minimally invasive sacral neuromodulation, or SNM, solutions. SNM therapy is primarily used to treat patients with overactive bladder, or OAB, fecal incontinence, or FI, and urinary retention, or UR. Our proprietary rechargeable SNM system, or our 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 OAB, FI, and UR. We believe our proprietary r-SNM System offers significant advantages, including being the first and only rechargeable SNM system that is designed to be 60% smaller than existing technology and to last approximately 15 years. We currently have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR, and expect to submit a pre-market approval, or PMA, application to the U.S. Food and Drug Administration, or FDA, for urinary urgency incontinence, or UUI, a predominant OAB subtype, during the first quarter of 2019. We believe our r-SNM System has the potential to disrupt and grow the approximately $605 million global SNM market in 2017, which is currently controlled by a single participant.

We are continuing to develop a growing body of compelling clinical evidence that demonstrates the safety, effectiveness, and sustained benefits of our r-SNM System. We have two clinical studies relating to our r-SNM System, a European study, RELAX-OAB, and a U.S. pivotal study, ARTISAN-SNM. In our clinical work to date, we have implanted 180 patients, with an additional 41 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. These patients are being evaluated at 14 centers in the United States and five in Europe. Out of 129 patients, 119 were directly implanted without an external trial period. We have determined the study's primary endpoint to be the percentage of test responders 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. All patients were evaluated as being "test responders" or "test failures" based on their therapy response at the one-month follow-up. "Test responders" were defined as showing at least a 50% reduction in urgency leaks on a three-day bladder diary at the one-month follow-up. 113 of the 129 patients, or approximately 88%, were determined to be test responders at the one-month follow-up. The remaining 16 of 129 patients, or approximately 12%, were determined to be test failures at the one-month follow-up. We have obtained partial three-month data for this study for 110 patients and 95 test responders. In these partial three-month results, therapy response rate was 96% for test responders and 87% for all patients, and 95% of test responders and 89% of all patients were "very" or "moderately" satisfied with the therapy. We expect that six-month results will be available in the first quarter of 2019. Further, we expect to submit our PMA application to the FDA during the first quarter of 2019. Typically, the PMA review process can take from six to 18 months, with the duration depending on a variety of factors. We plan to continue to collect long-term data out to two years, with the 12-month results anticipated to be available in the third quarter of 2019.

As part of the investigational device exemption, or IDE, approval process for our ARTISAN-SNM pivotal study, the FDA recommended that we should make several modifications to the study design in order for the study to serve as the primary clinical support for a future marketing approval. Although we have not modified

the ARTISAN-SNM pivotal study design to address all of the considerations that the FDA has reiterated, based on the preliminary study results to date, and assuming sufficiently strong results at six months and beyond, we believe we will be able to provide the FDA with reasonable assurance of the safety and effectiveness of our r-SNM System to support its marketing approval.

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 urinary urgency frequency, or UUF. The three-month results were published in the peer-reviewed *Journal of Neurourology and Urodynamics* in February 2018 and 12-month results have been submitted for publication. All patients were directly implanted and evaluated to determine if they were test responders, which was defined as showing at least a 50% reduction in the number of average leaks or voids per day or a reduction to less than eight voids per day, in each case on a three-day bladder diary, within one month. At three months, results for 48 patients who continued with study follow-up showed a therapeutic response rate of 91% for test responders and 71% for all implanted patients. The therapeutic response rate was sustained at 12 months for the 43 patients who continued with study follow-up, at 94% for test responders and 72% for all implanted patients. During the study, patients experienced clinically meaningful improvements in quality of life, and at 12 months, 84% of test responders and 77% of all patients were “very” or “moderately” satisfied with the therapy provided by our r-SNM System. We are following patients out to two years in this study and may follow patients out to five years at selected study sites.

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 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, an estimated 87 million adults suffer from OAB. The primary OAB subtypes are UUI and UUF. 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, a measure we believe to be generally accepted among the relevant physician community. FI is the inability to control bowel function that could lead to involuntary leakage from the rectum. In the United States and Europe, an estimated 40 million adults suffer from FI. Symptoms of OAB and FI 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 OAB and FI, 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.

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, and medication and other non-implantable treatments are better known to physicians and hospitals than SNM therapy. 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 Neurourology and Urodynamics, by 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 innovative and proprietary r-SNM System offers similar therapeutic benefits and competitive advantages to the only currently available SNM technology, InterStim II System, or InterStim II, offered by Medtronic plc, or Medtronic. We believe that our r-SNM System is the first and only system for SNM therapy with a rechargeable implantable pulse generator, or IPG, 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 on average every 4.4 years, as is the case for patients implanted with InterStim II, which we believe will significantly improve patient experience and reduce the risks of surgery and associated infections. In addition, we believe patients who have historically resisted SNM therapy because of the required multiple surgeries may be more inclined to be treated by our r-SNM System. Further, by reducing the number of replacement surgeries, physicians and facilities can utilize their resources more efficiently. Finally, our technology has the potential to significantly reduce overall costs to the healthcare system. In 2016, we commissioned a study that concluded that a rechargeable SNM system with a 15-year battery life could potentially reduce overall U.S. healthcare costs by up to $12 billion over a 15-year horizon.

We have designed and developed a proprietary method protected by patents, know-how, and trade secrets that enables us to combine ceramic and titanium for the IPG enclosure of our r-SNM System. This method enables us to incorporate a significantly smaller recharging coil into our IPG, which offers benefits such as 60% smaller size and half the weight of InterStim II and enhanced communication range. In addition, we also engineered our IPG to deliver constant current stimulation, which adapts to the body’s physiological changes, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. Further, our r-SNM System offers significant wireless charging benefits and an easy-to-use patient remote control. Finally, we designed and custom built a touchscreen clinician programmer that guides the implanting physician through electrode placement and stimulation programming. We also intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System. Our goals include introducing market differentiating 1.5T/3.0T magnetic resonance imaging, or MRI, full body conditional labelling for our r-SNM System, reducing by half the number of IPG battery recharging sessions required for the IPG to remain charged for one full month, introducing features that would enable us to connect our IPG to an already implanted InterStim II lead, and expanding the suite of product solutions available for SNM therapy over time.

Our r-SNM System consists of several components and accessories that provide a smoothly integrated, long-lasting, intuitive, and easy-to-use system. The miniaturized IPG 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 IPG and, if a temporary lead was used for the external trial period, implantation of the permanent lead. The IPG 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 IPG pocket and connected to the IPG. The IPG 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 IPG is wirelessly charged with an interval of approximately one hour once every two weeks under normal use conditions.

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. We plan to build a specialized and dedicated direct sales organization, which will initially target the estimated 850 physician specialists that represent a majority of the implant volume in the United States. We estimate that approximately 75% of U.S. implant volume is generated by less than 1,000 physicians. In addition, we plan to strategically

expand into international markets. We will initially endeavor to hire a specialty sales force of approximately 60 sales representatives in anticipation of our potentially receiving FDA approval to support the commercial launch of our r-SNM System in the United States. Further, we expect to grow our sales force over time and the number of our sales representatives at commercial launch will vary and may be higher depending on the duration of the PMA review process.

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 agreed to license to us certain patents and know-how, which we refer to collectively as 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, altogether which we refer to as, 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, InterStim I System, was introduced in 1997, over 300,000 patients have been implanted worldwide with such system and its successor InterStim II. In 2017, we believe that approximately 41,000 patients were implanted with SNM therapy, including 11,000 patients undergoing replacement implants, corresponding to an approximately $605 million global SNM market and approximately 8% year-over-year growth. With the global annual addressable 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 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 IPG 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 on average every 4.4 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. Finally, we believe that 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.

- ***Significant competitive and functional advantages over the only 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 for the IPG enclosure enables us to incorporate a significantly smaller recharging coil into our IPG, 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 adapts to the body's physiological changes, which we expect will provide a more consistent and

reliable therapy over time and reduce patient and physician management of the therapy. Further, our r-SNM System is differentiated by significant wireless charging benefits and an easy-to-use patient remote control. Finally, we designed and custom built a touchscreen clinician programmer that guides the implanting physician through electrode placement and stimulation programming. Our clinician programmer allows physicians to connect to a patient's IPG, while the patient is in the physician's care, to access key therapy data that is stored and maintained on the IPG.

- ***Strong clinical data***. We are continuing to develop 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 partial three-month results, therapy response rate was 96% for test responders and 87% for all patients. We expect that six- and 12-month results will be available in the first quarter of 2019 and the third quarter of 2019, respectively. Our European study, RELAX-OAB, evaluated 51 patients that suffered from UUF and UUI. At three months, results for 48 patients who continued with study follow-up showed a therapeutic response rate of 91% for test responders and 71% for all implanted patients. The therapeutic response rate was sustained at 12 months for the 43 patients who continued with study follow-up, at 94% for test responders and 72% for all implanted patients. We intend to follow patients for at least out to 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.

- ***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 marketing approval in Europe, Canada, and Australia for OAB, FI, and UR, and completed the enrollment and implantation of patients in our ARTISAN-SNM pivotal study. 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 30, 2018, we owned 17 issued U.S. patents and 20 issued foreign patents, and 17 pending U.S. patent applications and 59 pending foreign patent applications, and we licensed from AMF 30 issued U.S. patents and 38 issued foreign patents, and four pending U.S. patent applications and 28 pending foreign patent applications.

- ***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;
- Continue to promote awareness of our r-SNM System among healthcare providers;
- Build a commercialization infrastructure with a specialized direct sales and marketing team;
- Continuously innovate to introduce enhanced SNM product offerings and pursue expanded indications; and
- Further penetrate the addressable market by promoting patient and practice awareness.

Our Market

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

The market for SNM therapy is large and growing. We believe that the global SNM market was approximately $605 million in 2017, 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 41,000 patient implants, including 11,000 patients undergoing replacement implants, with nearly 90% of sales in this market being generated in the United States and approximately 85% of sales revenue coming from new implant volume. Further, we estimate that the global annual addressable SNM market is presently approximately one percent penetrated. We estimate the global addressable 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 U.S. market. We have regulatory approvals in Europe, Canada, and Australia for OAB, FI, and UR. We initially intend to pursue regulatory approval in the United States for UUI, a predominant OAB subtype, and we intend to seek regulatory approval for other indications in the United States in the future.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- We currently depend entirely on the successful and timely regulatory approval from the FDA and commercialization of our r-SNM System, our only product. Our r-SNM System may not receive

FDA regulatory approval or we may be significantly delayed in receiving regulatory approval. Even if we receive regulatory approval, we may not be able to successfully commercialize our r-SNM System.

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

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

- 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 if we are unable to establish, manage, and maintain sales and marketing capabilities, we will be unable to successfully commercialize our r-SNM System or generate product revenue.

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

- 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.

- 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.

- We will need to increase the size of our organization and we may be unable to manage our growth effectively.

- 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 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.

- 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.

- 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.

- Any side effects, manufacturing defects, misuse or abuse associated with our r-SNM System could result in patient injury or death.

- The size and future growth in the market for SNM therapy has not been established with precision and may be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market, our sales growth may be adversely affected.

- 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.

Preliminary Financial Results for the Three Months Ended September 30, 2018

We are currently finalizing our financial results for the three months ended September 30, 2018. While complete financial information and operating data are not yet available, set forth below are certain preliminary estimates of the results of operations that we expect to report for our third quarter of 2018. Our actual results may differ materially from these estimates due to the completion of our financial closing procedures, final adjustments and other developments that may arise between the date of this prospectus and the time the financial results for our third quarter of 2018 are finalized. All percentage comparisons to the prior year are measured to the midpoint of the range provided below for 2018.

For the three months ended September 30, 2018:

- Net revenue is expected to be approximately $0.2 million, an increase from approximately $0.1 million in the corresponding prior year period. The estimated increase in net revenue is related to the sale of our r-SNM systems to two new customers in Canada and one new customer in Europe.

- Loss from operations is expected to be between $7.5 million and $8.5 million, as compared to $4.5 million in the corresponding prior year period. The estimated increase in loss from operations is due primarily to the increase in general and administrative costs related to this offering and increased compensation, travel and other employee-related expenses related to increased headcount.

- Net loss is expected to be between $7.5 million and $8.5 million, as compared to $4.5 million in the corresponding prior year period. The estimated increase in net loss is due primarily to the factors described above.

As of September 30, 2018, our cash, cash equivalents and short-term investments is expected to be approximately $31.2 million and the principal and interest outstanding under our Loan Agreement, which is defined below, is expected to be approximately $10.1 million.

The estimates above represent the most current information available to management and do not present all necessary information for an understanding of our financial condition as of, and our results of operations for the three months ended, September 30, 2018. We have provided a range for certain of the preliminary results described above primarily because our financial closing procedures for the three months ended September 30, 2018 are not yet complete. As a result, our final results may vary from these preliminary estimates. We currently expect that our final results will be within the ranges or near the approximate amounts described above. It is

possible, however, that our final results will not be within these ranges or near the approximate amounts. These estimates are not necessarily indicative of any future period and should be read together with "Risk Factors," "Special Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Selected Historical Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus.

The preliminary financial data included in this prospectus has been prepared by, and is the responsibility of, our management and has not been reviewed or audited by our independent registered public accounting firm. Accordingly, our independent registered public accounting firm does not express an opinion or any other form of assurance with respect to this preliminary data.

Our consolidated financial statements as of and for the three months ended September 30, 2018 will not be available until after this offering is completed.

Recent Developments

In October 2018, we and Silicon Valley Bank entered into an amendment to the Loan Agreement, which is defined below, or the Loan Amendment, in connection with which we requested the full $5.0 million from Tranche B, which is defined below, and the full $5.0 million from Tranche C, which is defined below. We expect to receive the $10.0 million from both tranches prior to the completion of this offering. Pursuant to the Loan Amendment, Silicon Valley Bank has agreed to (i) extend the interest only period from June 30, 2019 to December 31, 2019, without requiring our receipt of a PMA in the United States for our r-SNM System, and (ii) make Tranche C available now instead of January 1, 2019. In addition, pursuant to the Loan Amendment, we are obligated to pay Silicon Valley Bank a fee of $100,000 in the event that we do not (i) consummate this offering with proceeds of no less than $75.0 million, (ii) receive PMA approval in the United States for our r-SNM System, or (iii) receive gross proceeds of at least $40.0 million from the sale of our equity securities, in each case on or prior to June 30, 2019. In addition, as a result of our request of the full $5.0 million from Tranche B and the full $5.0 million from Tranche C, the maturity of the Term Loan has been automatically extended to December 1, 2021. In connection with our request of the full $5.0 million from Tranche B and the full $5.0 million from Tranche C in October 2018, as of the date of this prospectus, each of the two warrants issued pursuant to the Loan Agreement will become exercisable for 33,333 shares of our Series C preferred stock when we borrow the $10.0 million from both tranches. The two warrants to purchase shares of our Series C preferred stock will convert into warrants to purchase 80,000 shares of our common stock in connection with the completion of this offering. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Indebtedness."

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 to take advantage of this transition period. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year following the fifth anniversary of the completion of this offering, (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 when we entered into the License Agreement. Our principal executive offices are located at 26 Technology Drive, Irvine, California 92618 and our telephone number is (949) 396-6322. Our website is www.axonicsmodulation.com. The information contained on or that can be accessed through our website is not incorporated by reference into this 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 common stock.

THE OFFERING	
Common stock offered by us	6,667,000 shares.
Common stock to be outstanding after this offering	25,305,600 shares (or 26,305,650 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 1,000,050 additional shares of our common stock at the public offering price less the estimated underwriting discounts and commissions.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $90.7 million (or approximately $104.6 million if the underwriters exercise their option to purchase additional shares in full), based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to (i) hire sales and clinical support personnel, including a specialty sales force of approximately 60 sales representatives, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval, to support the commercial launch of our r-SNM System in the United States, and to fund marketing initiatives in 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) the remainder for working capital and general corporate purposes. See “Use of Proceeds” for more information.
Risk factors	Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 17 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Reserved share program	At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to certain of our directors, officers, employees, business associates and related persons through a reserved share program. If these persons purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.
Proposed Nasdaq Global Market symbol	“AXNX.”

The number of shares of our common stock to be outstanding after this offering is based on 18,638,600 shares of common stock outstanding as of June 30, 2018, after giving effect to the conversion of all of our outstanding shares of preferred stock, and excludes as of that date:

- 1,425,316 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 $1.35 per share;
- 37,971 shares of our common stock reserved for future issuance under the 2014 Plan;
- 4,540,019 shares of our common stock reserved for future issuance under our 2018 Omnibus Incentive Plan, or the 2018 Plan, which became effective in October 2018; and
- 40,001 shares of our common stock issuable upon the exercise of outstanding warrants to purchase shares of our Series C preferred stock, which will convert into warrants to purchase 40,001 shares of our common stock in connection with the completion of this offering, at an exercise price of $7.50 per share.

In addition, the number of shares of our common stock after this offering does not give effect to 39,999 shares of our common stock issuable upon exercise of warrants to purchase shares of our Series C preferred stock, which will convert into warrants to purchase 39,999 shares of our common stock in connection with the completion of this offering, at an exercise price of $7.50 per share, that will become exercisable when we borrow an additional $10.0 million under the Loan Agreement with Silicon Valley Bank. As of the date of this prospectus, we have requested to borrow the additional $10.0 million and we expect to receive it prior to the completion of this offering.

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

- no exercise by the underwriters of their option to purchase up to an additional 1,000,050 shares of our common stock;
- no exercise of the outstanding stock options and warrants described above;
- a 1.2-for-1.0 forward stock split of our common stock effected on October 18, 2018;
- the automatic exchange of an aggregate of 27,229,768 ordinary shares of Axonics Europe, S.A.S., or Axonics Europe, into 310,500 shares of our Series A preferred stock, 604,560 shares of our Series B-1 preferred stock, 323,437 shares of our Series B-2 preferred stock, and 1,990,676 shares of our Series C preferred stock, which we refer to collectively as, the exchanged preferred stock, immediately prior to the completion of this offering as more specifically detailed under “Certain Relationships and Related Party Transactions—Share Exchange Agreement”;
- the automatic conversion of the warrants described above into warrants to purchase shares of our common stock upon the completion of this offering, the result of which will have no impact on our consolidated financial statements;
- the automatic conversion of all outstanding shares of our preferred stock, including all of the shares of the exchanged preferred stock, into 15,813,297 shares of our common stock upon the completion of this offering; and

- the filing of our amended and restated certificate of incorporation, or our certificate of incorporation, and the adoption of our amended and restated bylaws, or our bylaws, immediately prior to the completion of this offering.

Certain of our existing stockholders that are affiliated with certain of our directors have indicated an interest in purchasing an aggregate of up to approximately $45.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

SUMMARY FINANCIAL DATA

The following tables set forth, for the periods and as of the dates indicated, our summary financial data. Our consolidated statements of comprehensive loss for the years ended December 31, 2016 and 2017 are derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. We derived the summary consolidated statements of comprehensive loss for the six months ended June 30, 2017 and 2018, and the summary consolidated balance sheets data as of June 30, 2018, from our unaudited interim consolidated financial statements and related notes that are included elsewhere in this prospectus. We have prepared the unaudited information on the same basis as the audited consolidated financial statements and have included all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of our financial position and operating results for such period. Our historical results are not necessarily indicative of the results that may be expected or may actually occur in the future, and our interim results are not necessarily indicative of the expected results for future interim periods or the full year. You should read the following information together with the more detailed information contained in "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and the related notes included elsewhere in this prospectus.

The following table is presented in thousands, except for share and per share data:

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
			(unaudited)	
Statements of Comprehensive Loss:				
Net revenue	$ —	$ 128	$ —	$ 12
Cost of goods sold	—	118	—	5
Gross profit	—	10	—	7
Operating expenses				
Research and development	$ 12,510	$ 12,332	$ 5,827	$ 10,721
General and administrative	4,457	4,823	2,417	3,071
Sales and marketing	517	1,029	399	1,359
Total operating expenses	17,484	18,184	8,643	15,151
Loss from operations	(17,484)	(18,174)	(8,643)	(15,144)
Other income (expense), net	83	113	36	(108)
Net loss	$ (17,401)	$ (18,061)	$ (8,607)	$ (15,252)
Foreign currency translation adjustment	—	588	69	(3)
Comprehensive loss	$ (17,401)	$ (17,473)	$ (8,538)	$ (15,255)
Net loss per share, basic and diluted[1]	$ (7.52)	$ (7.04)	$ (3.60)	$ (5.43)
Weighted-average shares used to compute basic and diluted net loss per share[1]	2,313,526	2,564,964	2,389,066	2,811,183
Pro forma net loss per share, basic and diluted[1][2][3] (unaudited)		$ (0.98)		$ (0.82)
Pro forma weighted-average shares used to compute basic and diluted net loss per share[1][2][3] (unaudited)		18,378,261		18,624,480

(1) See Note 1 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the net loss per share and the number of shares used in the computation of the per share amounts.

(2) The pro forma net loss per share of common stock, basic and diluted, for the year ended December 31, 2017 and the six months ended June 30, 2018 reflects: (i) the automatic exchange of the exchanged preferred stock immediately prior to the completion of this offering, (ii) the automatic conversion of all outstanding shares of our preferred stock, including the exchanged preferred stock, into 15,813,297 shares of our common stock upon completion of this offering, (iii) the automatic conversion of outstanding warrants to purchase shares of our Series C preferred stock into warrants to purchase 40,001 shares of our common stock in connection with the completion of this offering, and the resulting reclassification of such warrants from a current liability to stockholders' equity (deficit), and (iv) the filing and effectiveness of our certificate of incorporation, which will occur immediately prior to the completion of this offering. Does not reflect (i) $10.0 million in additional borrowings we requested under the Loan Agreement in October 2018, which we expect to receive prior to the completion of this offering, and (ii) the related concurrent issuance of warrants to purchase shares of our Series C preferred stock, which will become exercisable for 39,999 shares of our common stock immediately prior to the closing of this offering at an exercise price of $7.50 per share.

(3) The pro forma net loss per share of common stock, basic and diluted, does not give effect to the issuance of shares of our common stock in this offering nor do they give effect to potential dilutive securities where the impact would be anti-dilutive.

The following table is presented in thousands:

	As of June 30, 2018		
	Actual (unaudited, restated)	Pro Forma(2) (unaudited)	Pro Forma as Adjusted(3)(4) (unaudited)
Balance Sheets Data(1):			
Cash, cash equivalents and short-term investments	$ 39,881	$ 39,881	$ 130,547
Property and equipment, net	1,459	1,459	1,459
Intangible asset, net	483	483	483
Total assets	45,800	45,800	136,466
Total liabilities	14,024	13,784	13,784
Convertible preferred stock	82,126	—	—
Noncontrolling interest in Axonics Europe S.A.S.	31,066	—	—
Stock subscription receivable(5)	(1,824)	(1,824)	(1,824)
Accumulated deficit	(82,418)	(82,418)	(82,418)
Total stockholders' equity (deficit)	(81,418)	32,015	122,681

(1) See Note 10 to our consolidated financial statements appearing elsewhere in this prospectus for more information on the restatements of certain of our consolidated financial statements, including our consolidated balance sheets.

(2) Gives effect to: (i) the automatic exchange of the exchanged preferred stock immediately prior to the completion of this offering, (ii) the automatic conversion of all outstanding shares of our preferred stock, including the exchanged preferred stock, into 15,813,297 shares of our common stock upon completion of this offering, (iii) the automatic conversion of outstanding warrants to purchase shares of our Series C preferred stock into warrants to purchase 40,001 shares of our common stock in connection with the

completion of this offering, and the resulting reclassification of such warrants from a current liability to stockholders' equity (deficit), and (iv) the filing and effectiveness of our certificate of incorporation, which will occur immediately prior to the completion of this offering. Does not reflect (i) $10.0 million in additional borrowings we requested under the Loan Agreement in October 2018, which we expect to receive prior to the completion of this offering, and (ii) the related concurrent issuance of warrants to purchase shares of our Series C preferred stock, which will become exercisable for 39,999 shares of our common stock immediately prior to the closing of this offering at an exercise price of $7.50 per share.

(3) Reflects, in addition to the pro forma adjustment set forth in footnote 2, the sale of 6,667,000 shares of our common stock in this offering at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and short-term investments, total assets and total stockholders' equity (deficit) by approximately $6.2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price, as set forth on the cover page of this prospectus, would increase (decrease) each of cash, cash equivalents and short-term investments, total assets and total stockholders' equity (deficit) by approximately $14.0 million, assuming the shares of our common stock offered by this prospectus are sold at the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price, the number of shares we sell, and other terms of this offering that will be determined at pricing.

(5) Includes outstanding secured full recourse promissory notes, or promissory notes, as of June 30, 2018, with an aggregate principal balance of $1,782,268.70, that were issued to us by certain of our executive officers and directors in exchange for the exercise of an aggregate of 1,653,196 shares of common stock pursuant to stock option awards. We have entered into debt forgiveness and cancellation of note agreements with certain of our executive officers and directors, including each of our named executive officers, to terminate each of their respective promissory notes and to forgive all respective obligations for payment thereof in connection with this offering. See "Certain Relationships and Related Party Transactions—Loans to Officers and Directors."

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this prospectus, including our consolidated financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in our common stock. The occurrence of any of the following risks could have a material and adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.

Risks Related to Our Business and Strategy

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

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

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

- whether we are required by the FDA or other similar regulatory authorities to conduct additional clinical studies or to modify the design of our current studies to support the approval of our r-SNM System;
- our success in educating physicians and patients about the benefits, administration and use of our r-SNM System;
- the timely receipt of necessary marketing approvals from the FDA and other similar regulatory authorities;
- achieving and maintaining compliance with all regulatory requirements applicable to our r-SNM System;
- the ability to raise additional capital on acceptable terms, or at all, if needed, to support the commercial launch of our r-SNM System;
- the acceptance by physicians and patients of the safety and effectiveness of our r-SNM System;
- our ability to successfully commercialize our r-SNM System;
- our ability to hire a sufficient number of talented sales representatives to sell our r-SNM System;

- the ability of our current manufacturers and any third parties with whom we may contract to manufacture our r-SNM System to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with applicable requirements; and

- the availability, perceived advantages, relative cost, relative safety and relative efficacy of competing products, such as InterStim II, or competing third-line therapies, such as BOTOX injections and PTNS.

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

- exclude patients with mixed urinary incontinence, or MUI, which means a patient has both stress urinary incontinence and UUI;

- use either a seven-day bladder diary or two separate three-day bladder diaries;

- use a 12-month primary effectiveness endpoint in order to account for the placebo effect and enable assessment of durability of the treatment effect;

- use all patients in whom an implant is attempted, not initial responders after one month, for primary efficacy analysis;

- use multiple imputation to account for missing primary endpoint data;

- revise the protocol to include details on statistical analysis methods for analyzing the primary and secondary endpoints, analysis population, method for handling missing endpoint data and sensitivities and poolability analyses;

- use a two-sided 95% confidence interval; and

- provide further justification for restarting with a new activation date after a lead issue.

In response, we have engaged with the FDA regarding its recommendation, including our latest IDE supplement, which we submitted to the FDA in September 2018 to address certain of its recommendations. As a result, we incorporated a number of recommended study modifications. However, to date we elected not to incorporate several of the recommended modifications based on what we believe are currently accepted urology practice guidelines and the design of previous OAB clinical studies accepted by the FDA. We believe certain of these modifications would have resulted in a study design that increased study site and patient burdens, decreased the feasibility of enrollment or were not clearly supported by available peer-reviewed literature or currently accepted urology practice guidelines. At this point in the study, some of the FDA's recommendations cannot be implemented. For example, we cannot exclude patients with MUI and we cannot change the three-day bladder diaries taken at baseline to seven-day bladder diaries. On October 19, 2018, the FDA approved our latest IDE supplement and removed certain of its prior study design recommendations. However, the FDA also continues to reiterate several of its recommended study modifications, including exclusion of patients with MUI, use of a seven-day bladder diary or two separate three-day bladder diaries, use of a 12-month primary effectiveness endpoint and use of all patients in whom an implant is attempted, instead of initial responders after one month, for our primary efficacy analysis. See "Business—Our Clinical Results and Studies—ARTISAN-SNM Pivotal Study" for more information.

Although we have not modified the ARTISAN-SNM pivotal study design to address all of the above considerations that the FDA has reiterated, based on the preliminary study results to date, and assuming

sufficiently strong results at six months and beyond, we believe we will be able to provide the FDA with reasonable assurance of the safety and effectiveness of our r-SNM system to support its marketing approval. However, it is possible that the results will not be sufficiently strong or that, in part due to its concerns with our study design, the FDA will not accept the data as reasonable assurance of safety and effectiveness, which would materially and adversely affect our ability to obtain marketing approval of our r-SNM System. If we intend to modify the study design to address any of the above FDA considerations that we have not already addressed, we will be required to obtain FDA approval of an IDE supplement before implementing the changes, which could result in significant delays. The approval requirements for an IDE supplement are generally the same as an original IDE, and they are approved if the FDA does not object within 30 days. We would also be required to get institutional review board, or IRB, approval of the protocol changes if the changes involve the rights, safety, or welfare of the patients, and some investigators may determine that local rules require additional approvals from a local IRB.

The FDA stated its belief that additional modifications were needed for our study design to support marketing approval, and recommended, but did not require, that we modify our study to address the issues described above. Incorporating such modifications may be costly or not possible at this point in the ongoing clinical study or lead to delays in obtaining approval from the FDA, which may be significant and adversely and materially affect our ability to successfully commercialize our r-SNM System. Further, even if we make changes to the study design to address these considerations, the FDA may not approve our r-SNM System.

In addition to our anticipated submission of a PMA based on data from the IDE process, on January 9, 2018, we also submitted to the FDA a premarket approval application, which we refer to as the “literature-based PMA,” in which equivalence to an already FDA approved product is claimed based on the review of technical specifications, published clinical studies, and other information. In our filing, we are claiming equivalence to the only FDA approved SNM device, InterStim II. On May 9, 2018, the FDA responded and requested that we submit additional information to demonstrate that our r-SNM device is sufficiently similar to the InterStim II device referenced in the literature to be able to determine safety and effectiveness from the literature. The FDA’s response also asked us to address a number of other matters, including those related to the electrical safety, electromagnetic compatibility and wireless technology, biocompatibility, and our pre-clinical studies. On October 18, 2018, we responded to the FDA and voluntarily withdrew the literature-based PMA. Subsequent to further consultation with the FDA, which is pending, we will evaluate the merits of submitting a new literature-based PMA application, if at all.

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

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

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

We have not derived meaningful revenue from our operations, as our activities have consisted primarily of developing our technology and conducting clinical studies. As a result, for the years ended December 31, 2016 and 2017, we recorded net losses of $17.4 million and $18.1 million, respectively, and for the six months ended June 30, 2017 and 2018, we recorded net losses of $8.6 million and $15.3 million, respectively. As of June 30, 2018, we had an accumulated deficit of $82.4 million. To date, we have financed our operations primarily through preferred stock financings and amounts borrowed under the Loan Agreement. We have devoted substantially all of our financial resources to research and development activities as well as general and administrative expenses associated with our operations, including clinical and regulatory initiatives to obtain marketing approval.

Following this offering, we expect that our operating expenses will continue to increase as we (i) build our commercial infrastructure, (ii) develop, enhance, seek FDA regulatory approval for, and begin to commercialize, if approved, our r-SNM System in the United States, (iii) increase our commercialization efforts internationally, and (iv) incur additional operational costs associated with being a public company. For example, we intend to hire approximately 60 sales representatives, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval to support the commercial launch of our r-SNM System in the United States and expect to grow our sales force over time and the number of our sales representatives at commercial launch will vary and may be higher depending on the duration of the PMA review process. If we are delayed in obtaining approval of our r-SNM System by the FDA, we may be required to offer increased compensation to our U.S. sales team in order to retain them, which would further increase our operational costs. As a result, we expect to continue to incur operating losses for the foreseeable future. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

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

Our r-SNM System is currently our sole product, and we are completely dependent on the success of our r-SNM System. We have limited experience marketing and selling our r-SNM System, and if we are unable to establish, manage, and maintain sales and marketing capabilities, we will be unable to successfully commercialize our r-SNM System or generate 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 complete our ARTISAN-SNM pivotal study and to obtain regulatory approval in the United States for our r-SNM System for the treatment of UUI;
- the effectiveness of our marketing and sales efforts in the United States and internationally;
- our third-party manufacturers’ and suppliers’ ability to manufacture and supply the components of our r-SNM System in a timely manner and in accordance with our specifications;

- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing therapies;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to our r-SNM System;
- the emergence of competing technologies and other adverse market developments, and our need to enhance our r-SNM System and/or develop new products to maintain market share in response to such competing technologies or market developments;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our r-SNM System; and
- our ability to successfully conduct additional clinical studies as may be required by the FDA or comparable non-U.S. regulatory authorities to enable our r-SNM System to be approved for additional indications.

We currently have a limited sales and marketing organization outside the United States and we do not have a sales or marketing organization in the United States. We began marketing and selling our r-SNM System in certain limited European markets in 2018. As a result, we have limited experience marketing and selling our r-SNM System. We currently sell our r-SNM System through a limited direct sales force in Europe, that targets physicians and hospitals. As of September 30, 2018, our limited direct sales organization in Europe consisted of four employees.

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

Once hired, the training process for sales representatives can be lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with our product expected by physicians. Upon completion of the training, we expect that the sales representatives would require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent we hire personnel from our competitor, we may have to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. This may subject us to allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Addressing such allegations would be costly both in terms of time and resources. Any of these risks may adversely affect our business.

If we are not successful in recruiting sales, marketing and reimbursement personnel or building a sales and marketing infrastructure, we will have difficulty successfully commercializing our r-SNM System, which

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

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

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development activities and conducting clinical studies for our r-SNM System. We expect these activities and the associated expenses to continue following this offering. We also expect our expenses to increase substantially in connection with our plan to commercialize our r-SNM System in the United States and internationally. Additional expenditures will also include costs associated with manufacturing and supply, sales and marketing costs, costs and expenses incidental to being a public company, and general operations. In addition, other unanticipated costs may arise.

As of June 30, 2018, we had cash, cash equivalents and short-term investments of $39.9 million. We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months.

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

- our ability to successfully complete our ARTISAN-SNM pivotal study and to obtain regulatory approval in the United States for our r-SNM System for the treatment of UUI and the associated costs;
- the costs associated with manufacturing, selling, and marketing our r-SNM System for the treatment of UUI in the United States, if approved by the FDA, and for other indications for which we receive regulatory clearance or approval, including the cost and timing of implementing our sales and marketing plan and expanding our manufacturing capabilities;
- our ability to effectively market and sell, and achieve sufficient market acceptance and market share for, our r-SNM System;
- the costs to establish, maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;
- the emergence of competing technologies and other adverse market developments, and our need to enhance our r-SNM System and/or develop new products to maintain market share in response to such competing technologies or market developments;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the time and cost necessary to complete post-market studies that could be required by regulatory authorities or other studies required to obtain clearance for additional indications;
- the timing, receipt, and amount of license fees and sales of, or royalties on, or future improvements on our r-SNM System, if any; and

- our need to implement additional internal systems and infrastructure, including financial and reporting systems, incidental to being a public company.

We may need to raise additional capital or alternatively we may seek to raise only equity capital. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our r-SNM System, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we are unable to obtain adequate financing when needed and on terms that are acceptable to us, we may have to delay, reduce the scope of or suspend the implementation of our sales and marketing plan and our ongoing research and development efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

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

On October 1, 2013, we entered into the License Agreement pursuant to which AMF agreed to license to us the AMF IP to develop and commercialize the AMF Licensed Products. Any and all improvements to the AMF IP made by us will be owned by AMF and licensed to us under the License Agreement for purposes of making AMF Licensed Products.

Pursuant to the License Agreement, AMF granted us a royalty-bearing, sublicensable (by written, executed agreements only, subject to the terms of the License Agreement) license, under the AMF IP to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of (i) chronic pain in humans through the application of electrical energy to the nervous system, (ii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve, a nerve that interfaces with parasympathetic control of the heart, lungs and digestive tract and (iii) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system. We have the right to expand the field of use for the AMF IP to the (i) treatment of any condition (other than inflammatory conditions) in humans through the application of electrical energy to the vagus nerve or anywhere else in the body other than the vagus nerve, and (ii) 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.

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.

Pursuant to the License Agreement, we are obligated to pay a 4% royalty of all net revenue derived from the AMF Licensed Products if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case, subject to certain adjustments.

In 2017, we sold several of our r-SNM Systems as part of a one-time evaluation agreement with a hospital in Canada. As a result, we generated net revenue of $128,118 and recorded related royalties of $4,972 during the fiscal year ended December 31, 2017. No revenue was generated and no payments were made during the fiscal year ended December 31, 2016. In addition, beginning in 2018, we are required to pay AMF a minimum annual royalty, or the Minimum Royalty, payable quarterly if the royalty due is in excess of the Minimum Royalty, which will automatically increase each calendar year thereafter, subject to a maximum amount of $200,000 per year. We have accrued $37,500 as of June 30, 2018 toward AMF Minimum Royalties.

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF the greater of (i) the amount of the 4% royalty referred to above, and (ii) the Minimum Royalty for such calendar year beginning with 2018. We have 60 days to pay AMF this amount, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

The License Agreement was amended twice in February 2014, once in connection with our Series A preferred stock financing, in order to, among other things, include the field of the treatment of urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, within the scope of the licenses granted therein, an option under the License Agreement that required us to pay $1.0 million. In consideration for the inclusion of this field with the scope of the licenses granted in License Agreement, we issued AMF 50,000 shares of our Series A preferred stock.

As of June 30, 2018, AMF holds 888,000 shares of our common stock, 125,000 shares of our Series A preferred stock, and 771,161 shares of our Series B-1 preferred stock. John Petrovich, a member of our board of directors, is the President, Chief Executive Officer, Senior Vice President of Business Development, and General Counsel of AMF. For additional information about the License Agreement, see “Business—AMF License Agreement.”

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

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

In the event of certain termination by AMF, 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.

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

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

For over 20 years, physicians and patients have relied on the only approved SNM therapy offered by Medtronic plc, or Medtronic, InterStim II and its predecessor, InterStim I. As our r-SNM System will be a new product in the SNM market, our primary strategy to penetrate the market and grow our revenue is to drive physician and patient awareness of the material benefits of our r-SNM System. Physicians and patients may choose not to adopt our r-SNM System for a number of reasons, including:

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

- marketing and other efforts by Medtronic targeting physicians, including those with whom they have long-term relationships; and
- ineffectiveness of our sales and marketing efforts for our r-SNM System.

In addition, patients may choose not to adopt SNM therapy as a potential therapy if, among other potential reasons, their anatomy would not allow for effective treatment with our r-SNM System, they are reluctant to receive an implantable device as opposed to an alternative, non-implantable treatment, or they are worried about potential adverse effects of SNM therapy, such as infection, discomfort from the stimulation, or soreness or weakness.

We intend to focus the majority of our sales and marketing efforts in the United States where reimbursement for SNM therapy is well established and covered by most major U.S. insurers. We plan to build a specialized and dedicated direct sales organization, which will initially target the estimated 850 physician specialists that represent a majority of the implant volume in the United States. We estimate that approximately 75% of U.S. implant volume is generated by less than 1,000 physicians. In addition, we plan to strategically expand into international markets. We will initially endeavor to hire a specialty sales force of approximately 60 sales representatives in anticipation of our potentially receiving FDA approval to support the commercial launch of our r-SNM System in the United States. Further, we expect to grow our sales force over time and the number of our sales representatives at commercial launch will vary and may be higher depending on the duration of the PMA review process.

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 IPG, constant current technology, improved patient experience, and simplified physician implantation and programming. We believe that educating healthcare providers and patients about the clinical merits and patient benefits of our r-SNM System as a treatment for OAB will be key elements driving adoption of our r-SNM System. However, some physicians may have prior history with or a preference for other treatment options. Moreover, our efforts to educate the medical community and patients on the benefits of our r-SNM System will require significant resources and we may never be successful. If healthcare providers and patients do not adopt our r-SNM System, and our r-SNM System does not achieve broad market acceptance, our ability to execute our growth strategy will be impaired, and our business and future prospects may be adversely affected.

We will compete against other companies offering first-, second- and third-line therapies for the treatment of OAB, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration and improved operating results.

The medical technology industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Our competitors have historically dedicated and will continue to dedicate significant resources to promoting their products and developing new products or methods to treat OAB and FI. We consider our primary competition to be implantable SNM devices designed to treat OAB or FI. InterStim II is the only currently implantable SNM device approved for commercialization in the United States by the FDA, is approved for the treatment of UUI and UUF, FI and UR, and, together with its predecessor InterStim I, has been available to and used by physicians for over 20 years. Medtronic, the maker of InterStim II, is a major medical device company that has substantially greater financial,

technical, sales and marketing resources than we do. The global SNM market was estimated to be approximately $605 million in 2017, which we believe is comprised of sales of SNM systems for the treatment of UUI, UUF, FI, and UR, with the United States comprising nearly 90% of the market. Given the size of the existing and potential market in the United States, we expect that as we prepare to initiate our commercial launch in the United States, Medtronic will take aggressive action to protect its current market position, which could include pursuing full body MRI and developing a rechargeable SNM device in the near future or significantly accelerating its existing plans to pursue any of these product initiatives. If Medtronic were to develop a new device that is comparable to, or more competitive than, our r-SNM System in terms of size, battery life, patient and physician ease of operation, cost and other features, the physician and patient community may prefer Medtronic's new device over ours due to a variety of factors, including familiarity with, and loyalty to, Medtronic. Additionally, we expect that Medtronic will engage in significant marketing and other efforts with physicians, many of whom they have long-term relationships with, to promote InterStim II and any other future SNM device Medtronic could develop and prevent, delay or reduce adoption of our r-SNM System. We believe other businesses, such as Nuvectra, may be in various stages of developing SNM devices designed to treat OAB or FI. If we are successful in obtaining FDA approval for our r-SNM System, we will face significant competition in establishing our market share in the United States and may encounter unforeseen obstacles and competitive challenges in the United States.

We will also compete with other less invasive third-line treatments, such as BOTOX injections and PTNS. In addition, emerging businesses may be in the early stages of developing additional SNM devices or therapies designed to treat OAB or FI. We will also compete with invasive surgical treatment options, such as augmentation cystoplasty, which is a procedure that increases the size of the bladder.

Many of the companies against which we will compete, including Medtronic, may have competitive advantages with respect to primary competitive factors in the market, including:

- greater company, product, and brand recognition;
- more readily accessible sources of additional capital on attractive terms;
- longer history of InterStim II use and physician familiarity with existing products and treatments;
- broader regulatory approvals and more approved indications;
- superior product safety, reliability, and durability;
- better quality and larger volume of clinical data;
- more effective marketing to, and education of, patients, physicians, and hospitals;
- greater patient comfort;
- more sales force experience and greater market access;
- better product support and service;
- more advanced technological innovation, product enhancements, and speed of innovation;
- more effective pricing and revenue strategies;
- lower procedure costs to patients; and
- dedicated practice development.

Our r-SNM System is a third-line therapy for the treatment of OAB in patients who have failed, been contraindicated or refractory for, conservative first- and second-line therapies, such as lifestyle modifications, behavioral changes or medications. 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. We may also face competition from pharmaceutical companies that develop new pharmacological therapies to treat OAB. 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.

We have not pursued regulatory approval in the United States of our r-SNM System for indications other than for the treatment of UUI, which may limit adoption of our r-SNM System, and if we are unable to obtain approval for indications in addition to our potential approval for UUI, our marketing efforts for our r-SNM System will be limited.

We have not pursued regulatory approval in the United States for our r-SNM System for indications other than for the treatment of UUI. InterStim II is currently approved in the United States for the treatment of UUI, UUF, FI, and UR. Physicians that are familiar with and use InterStim II may not adopt our r-SNM System because they will not be able to use it on-label to treat UUF, FI, or UR. If we are unable to obtain regulatory approval for indications in addition to our potential approval for UUI, our marketing efforts for our r-SNM System and ability to drive adoption among physicians familiar with InterStim II may be severely limited. As a result, we may not generate physician and patient demand or approval of 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 IPG 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 on average every 4.4 years, as is the case for patients implanted with the non-rechargeable InterStim II. Our proprietary method of combining ceramic and titanium for the IPG enclosure enables us to incorporate a significantly smaller recharging coil into our IPG, 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 adapts to the body's physiological changes, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. Further, our r-SNM System is differentiated by significant wireless charging benefits and an easy-to-use patient remote control. Finally, we designed and custom built a touchscreen clinician programmer that guides the implanting physician through electrode placement and stimulation programming. Our clinician programmer allows physicians to connect to a patient's IPG, while the patient is in the physician's care, to access key therapy data that is stored and maintained on the IPG.

However, these advantages may not be perceived as well as we expect by patients and physicians. As a result, we may need to compete on the basis of price or other factors, which may negatively impact market reaction to our r-SNM System. For example, the decreasing prices may cause patients and physicians to perceive our r-SNM System to be of lower quality than InterStim II, which could limit widespread adoption and acceptance of our r-SNM System. Moreover, price competition would also likely render sales of our r-SNM System less profitable. Any of these consequences could adversely affect our business, financial condition and results of operations.

Our long-term growth depends, in part, on our ability to develop and enhance our r-SNM System, and if we fail to do so we may be unable to compete effectively.

It is important to our business and our long-term growth that we continue to develop and enhance our r-SNM System. We intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System. Our goals include introducing market differentiating 1.5T/3.0T MRI full body conditional labelling for our r-SNM System, reducing by half the number of IPG battery recharging sessions required for the IPG to remain charged for one full month, introducing features that would enable us to connect our IPG to an already implanted InterStim II lead, and expanding the suite of product solutions available for SNM therapy over time. Additionally, we intend to pursue regulatory approval for other indications in the United States in the future.

Developing enhancements to our r-SNM System can be expensive and time-consuming and could divert management's attention away from the commercialization of our r-SNM System and divert financial resources from other operations. The success of any new product enhancements, including approval of our r-SNM System for additional indications, will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs, and develop new product enhancements to meet those needs;
- demonstrate, if required, the safety and effectiveness of new enhancements to our r-SNM System, including additional indications, with data from preclinical studies and clinical studies;
- obtain, and obtain in a timely manner, the necessary regulatory clearances or approvals for new enhancements to our r-SNM System, product modifications or expanded indications for our r-SNM System;
- avoid infringing upon the intellectual property rights of third-parties;
- be fully FDA-compliant with marketing of new devices or modified products;
- competitive counter moves advanced by Medtronic to secure and maintain customers;
- develop an effective and dedicated sales and marketing team to provide adequate education and training to potential users of our r-SNM System; and
- receive adequate coverage and reimbursement for procedures performed with our r-SNM System.

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

We will need to increase the size of our organization and we may be unable to manage our growth effectively.

We have been growing rapidly in recent periods and have a relatively short history of operating as a commercial company. As of September 30, 2018, we had 72 employees. We expect to hire and train new personnel as we continue to grow and expand our operations. Primarily, we plan to build a specialized and dedicated direct sales organization. We will initially endeavor to hire a specialty sales force of approximately 60 sales representatives in anticipation of our potentially receiving FDA approval to support the commercial launch of our r-SNM System in the United States. However, we may not be able to hire a sufficient number of sales

representatives to support our U.S. commercial operations in time for commercial launch or at all. Further, we expect to grow our sales force over time. Any failure by us to manage our growth effectively or to hire a sufficient number of sales representatives and the number of our sales representatives at commercial launch will vary and may be higher depending on the duration of the PMA review process, 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 and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

In addition, as a public company, we will need to support managerial, operational, financial and other resources to manage our operations, commercialize our r-SNM System and continue our research and development activities. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth, and this growth may place significant strain on us. Successful growth will also be dependent upon our ability to implement appropriate financial and management controls. Due to our limited financial resources and 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, possibly materially. If our estimates and projections overestimate the size of this market, our sales growth may be adversely affected.

Our estimates of the size and future growth in the market for SNM therapy, including the number of people in the United States and Europe who suffer from symptoms of either OAB or FI and who are readily treatable with and eligible candidates for SNM therapy, is based on a number of internal and third-party studies, reports and estimates. In addition, our internal estimates are based in large part on current treatment patterns by

healthcare providers using SNM therapy and our belief that the incidence of OAB and FI in the United States, Europe and worldwide is increasing. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for SNM therapy and our r-SNM System, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. The actual numbers of people with OAB and FI who are readily treatable with and eligible candidates for SNM therapy, and the actual demand for our r-SNM System or competitive products, could differ materially from our projections if our assumptions are incorrect. As a result, our estimates of the size and future growth in the market for our r-SNM System may prove to be incorrect. If the actual number of people with OAB and FI who would benefit from our r-SNM System and the size and future growth in the market for our r-SNM System is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business. Additionally, while we have regulatory approvals in Europe, Canada, and Australia for OAB, FI, and UR, we initially intend to pursue regulatory approval in the United States for UUI, a predominant OAB subtype, and we intend to seek regulatory approval for other indications in the United States in the future.

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

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

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

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such

litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

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

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

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience;
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and
- unanticipated or undisclosed liabilities of any target.

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

The implementation of a new enterprise resource planning system could cause disruption to our business and operations.

We are in the process of implementing a new enterprise resource planning system, or ERP system. This system will integrate our operations, including supply-chain, order entry, manufacturing, inventory and financial reporting, among others. ERP system implementations are complex projects that require significant investment of capital and human resources, the reengineering of many business processes and the attention of many employees who would otherwise be focused on other aspects of our business. Any disruptions, delays or deficiencies in the design and implementation of the improvements to our ERP system may result in potentially much higher costs than anticipated and may adversely affect our ability to develop and launch solutions, fulfill contractual obligations, file reports with the Securities and Exchange Commission, or SEC, in a timely manner or otherwise operate our business and our controls environment. Moreover, despite our security measures, our information technology systems, including the ERP system, are vulnerable to damage or interruption from fires, floods and other natural disasters, terrorist attacks, computer viruses or hackers, power losses and computer system or data network failures, which could result in significant data losses or theft of sensitive or proprietary information. Any of these consequences may harm our business.

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 IPG 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 the Loan and Security Agreement, or the Loan Agreement, with Silicon Valley Bank providing for a term loan, or the Term Loan. Pursuant to the Loan Agreement, we may request up to $20.0 million in three tranches of term loans, with such drawn obligations maturing on June 1, 2021. We requested $10.0 million from the first tranche, or Tranche A, simultaneously with the entry into the Loan Agreement, which is currently outstanding. We may request an additional $5.0 million, or Tranche B, after the date commencing on the later of (i) the date that we achieve positive three-month results in our

ARTISAN-SNM pivotal study, as confirmed to Silicon Valley Bank by a member of our management team and a member of our board of directors, and (ii) July 1, 2018, and ending on December 31, 2018, and another $5.0 million, or Tranche C, and together with Tranche A and Tranche B, the Tranches, after the date commencing on the later of (i) the date that Silicon Valley Bank receives evidence, in form and substance reasonably satisfactory to Silicon Valley Bank, that we have received our PMA in the United States for our r-SNM System or gross proceeds from the sale of our equity securities of not less than $20.0 million (which condition was satisfied when we issued and sold 2,233,333 shares of our Series C preferred stock in March 2018 for aggregate gross proceeds of $20,099,997), and (ii) January 1, 2019, and ending on March 31, 2019, subject to certain terms and conditions. If either Tranche B or Tranche C is drawn, then the maturity of the Term Loan is automatically extended to December 1, 2021.

The Loan Agreement provides for monthly interest payments through December 31, 2018; provided that, (i) if we request and Silicon Valley Bank funds Tranche B or Tranche C, this interest-only period automatically extends through June 30, 2019, and (ii) if we have received a PMA in the United States for our r-SNM System and we request and Silicon Valley Bank funds Tranche C, the interest-only period automatically extends through December 31, 2019. On the first day of the end of the interest only period, 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%.

In October 2018, we and Silicon Valley Bank entered into an amendment to the Loan Agreement, or the Loan Amendment, in connection with which we requested the full $5.0 million from Tranche B and the full $5.0 million from Tranche C. Pursuant to the Loan Amendment, Silicon Valley Bank has agreed to (i) extend the interest only period from June 30, 2019 to December 31, 2019, without requiring our receipt of a PMA in the United States for our r-SNM System, and (ii) make Tranche C available now instead of January 1, 2019. In addition, pursuant to the Loan Amendment, we are obligated to pay Silicon Valley Bank a fee of $100,000 in the event that we do not (i) consummate this offering, with proceeds of no less than $75.0 million, (ii) receive PMA approval in the United States for our r-SNM System, or (iii) receive gross proceeds of at least $40.0 million from the sale of our equity securities, in each case on or prior to June 30, 2019. In addition, as a result of our request of the full $5.0 million from Tranche B and the full $5.0 million from Tranche C, the maturity of the Term Loan has been automatically extended to December 1, 2021.

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

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

its security interest and liquidate some or all of the collateral, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

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

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

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

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

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

If our r-SNM System is approved in the United States, to ensure adequate inventory supply, we must forecast inventory needs and place orders with suppliers based on our estimates of future demand for our r-SNM System. If approved in the United States, we anticipate there will be an increased demand for our r-SNM System, and our limited historical experience in foreign markets may not provide us with enough data to accurately predict future demand. Our ability to accurately forecast demand for our r-SNM System could be negatively affected by many factors, including our failure to adequately manage our expansion efforts, product introductions by competitors, an increase or decrease in customer demand for our r-SNM System or for products of our

competitors, our failure to accurately forecast customer acceptance of new product enhancements, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Similarly, a portion of our inventory could become obsolete or expire, which could have a material and adverse effect on our earnings and cash flows due to the resulting costs associated with inventory impairment charges and costs required to replace obsolete inventory. Any of these occurrences could negatively impact our financial performance.

Conversely, if we underestimate customer demand for our r-SNM System, we may not be able to deliver sufficient products to meet our customers' requirements, which could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or our third-party manufacturers may not be able to allocate sufficient resources to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our r-SNM System and our results of operations.

We rely on third parties for the manufacture of our r-SNM System. This reliance on third parties increases the risk that we will not have sufficient quantities of our r-SNM System or such quantities at an acceptable cost, and reduces our control over the manufacturing process, which could delay, prevent, or impair our development or commercialization efforts.

We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of certain components of our r-SNM System. For our off-the-shelf components, we do not have long-term supply agreements with many of our third-party manufacturers, and we purchase certain components of our r-SNM System on a purchase order basis. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third party to manufacture any such component of our r-SNM System according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our r-SNM System or otherwise do not satisfactorily perform according to the terms of the agreements and/or purchase orders between us and them;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party manufacturers of our agreements with them;
- the failure of third-party manufacture to comply with applicable regulatory requirements;
- the possible failure of the third-party to manufacture such component of our r-SNM System according to our specifications; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with current Good Manufacturing Practice, 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 develop, obtain marketing approval for or market our r-SNM System. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely harm our business and results of operations.

Any performance failure on the part of our existing or future manufacturers could delay marketing approval. We do not currently have arrangements in place for redundant supply of certain components of our r-SNM System. If our current third-party manufacturers cannot perform as agreed, we may be required to replace those manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture these components, we may incur added costs and delays in identifying and qualifying any such replacement.

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

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

The manufacturing process of our r-SNM System includes sourcing components from various third-party suppliers, assembly and testing. We must manufacture and assemble these systems in compliance with regulatory requirements and at an acceptable cost in order to achieve and maintain profitability. We have only a limited history of manufacturing and assembling our r-SNM System and, as a result, we may have difficulty manufacturing and assembling this system in sufficient quantities in a timely manner. To manage our manufacturing and operations with our suppliers, we will need to forecast anticipated product orders and material requirements to predict our inventory needs from six months to a year in advance and enter into purchase orders on the basis of these requirements. Our limited manufacturing history may not provide us with enough data to accurately predict future component demand, fluctuations in availability and pricing of commodity materials of supply, and, to anticipate our costs and supply needs effectively. We may in the future experience delays in obtaining components from suppliers, which could impede our ability to manufacture and assemble our r-SNM System on our expected timeline. As a result of this or any other delays, we may encounter difficulties in production of our r-SNM System, including problems with quality control and assurance, component supply shortages or surpluses (including with respect to the ceramic and titanium we use in our r-SNM System), increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements.

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

Expedited, reliable shipping will be essential to our operations. We intend to rely heavily on providers of transport services for reliable and secure point-to-point transport of our r-SNM System to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of our r-SNM System, it would be costly to replace our r-SNM System in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our r-SNM System and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our r-SNM System on a timely basis.

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

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and internationally or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, consultants and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our r-SNM System at prices necessary to support our current business strategies.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payors. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for price concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals and ambulatory surgery centers, or ASCs. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our future customers, which may exert further downward pressure on the prices of our r-SNM System.

To successfully market and sell our r-SNM System in markets outside of the United States, we must address many international business risks with which we have limited experience, and failure to manage these risks may adversely affect our operating results and financial condition.

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

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

- reduced or varied protection for intellectual property rights in some countries;
- export restrictions, trade regulations, and foreign tax laws;
- fluctuations in foreign currency exchange rates;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- customs clearance and shipping delays;
- political, social, and economic instability internationally, terrorist attacks, and security concerns in general;
- preference for locally manufactured products;
- potentially adverse tax consequences, including the complexities of foreign value-added tax, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;
- the burdens of complying with a wide variety of foreign laws and different legal standards;
- increased financial accounting and reporting burdens and complexities; and
- FCPA, OFAC, the Bribery Act, each of which is defined below, and other export control, anti-corruption, anti-money laundering and anti-terrorism laws and regulations.

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

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

Our success will depend in part on our continued ability to retain and motivate our highly qualified management, clinical, and other personnel. We are highly dependent upon our management team, particularly our Chief Executive Officer and member of our board of directors, Raymond W. Cohen, and the other members of our senior management, and other key personnel. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. The replacement of any of our key personnel would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives, which could have an adverse effect on our business. In addition, we do not carry any “key person” insurance policies that could offset potential loss of service under applicable circumstances.

Many of our employees have become or will soon become vested in a meaningful amount of our common stock or common stock options. Our employees may be more likely to leave us if the shares they own or have the option to purchase have significantly appreciated in value relative to the original purchase price for the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements entered into in connection with this offering, as described herein. 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.

Third-party payors and physicians who do not cover or use our r-SNM System may require additional clinical data prior to adopting or maintaining coverage of our r-SNM System.

Our success depends on third-party payors and physician acceptance of our r-SNM System as an effective treatment option for patients with OAB. If third-party payors or physicians do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for our r-SNM System.

In addition, certain physicians, hospitals, ASCs and third-party payors may prefer to see longer-term safety and effectiveness data than we have produced or may be able to produce. Any data that we or others may generate in the future may not be consistent with that observed in our existing clinical studies.

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 are in the process of implementing policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. Our policies and procedures may not be sufficient to ensure that our directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, or that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.

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

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research

and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.

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

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the TCJA, was signed into law, significantly reforming the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a territorial system and modifies or repeals many business deductions and credits. We continue to examine the impact the TCJA may have on our business. We are in the process of evaluating the effect of the TCJA on our projection of minimal cash taxes or to our net operating losses. The estimated impact of the TCJA is based on our management's current knowledge and assumptions and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. The impact of the TCJA on holders of our common stock remains uncertain and could be adverse. There remains significant uncertainty as to the impact of the TCJA on us and on any investment in our common stock. We urge the purchasers of our common stock in this offering 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, pre-market clearance and approval, record keeping procedures, advertising and promotion, recalls and field safety corrective actions, post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury, post-market approval studies, and product import and export.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. Our failure to comply with all applicable regulations could jeopardize our ability to sell our r-SNM System and result in enforcement actions such as warning letters, fines, injunctions, civil penalties, termination of distribution, recalls or seizures of products, delays in the introduction of products into the market, total or partial suspension of production, refusal to grant clearances or approvals, withdrawals or suspensions of approvals, prohibitions on sales of our r-SNM System, and in the most serious cases, criminal penalties.

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

of our r-SNM System to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in costly remediation efforts, requirements that we complete government mandated clinical studies or government enforcement actions.

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

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

As an active-implantable device, our r-SNM System is subject to the most stringent degree of medical device regulation. The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of medical device products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, with regulations differing from country to country. In the process of obtaining PMA approval, which is required for our r-SNM System, the FDA must determine that a proposed device is safe and effective for its intended use based in part on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. In addition, if we were to pursue regulatory approvals for additional indications for our r-SNM System, we would be required to conduct additional clinical studies or pre-clinical studies to support such indications, which would be time-consuming and expensive, and may produce results that do not support such regulatory approvals.

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

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

If our r-SNM System is approved in the United States through the PMA pathway, any modification to or additional indications for our r-SNM System that were not previously approved may require us to submit an additional PMA or PMA supplement and obtain FDA approval prior to implementing the change. If the FDA requires us to go through a lengthier, more rigorous examination, make modifications to the device, generate additional data to submit to the FDA or additional indications for approved products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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

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

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

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

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

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

diaries taken at baseline to seven-day bladder diaries. On October 19, 2018, the FDA approved our latest IDE supplement and removed certain of its prior study design recommendations. However, the FDA also continues to reiterate several of its recommended study modifications, including exclusion of patients with MUI, use of a seven-day bladder diary or two separate three-day bladder diaries, use of a 12-month primary effectiveness endpoint and use of all patients in whom an implant is attempted, instead of initial responders after one month, for our primary efficacy analysis. See “Business—Our Clinical Results and Studies—ARTISAN-SNM Pivotal Study” for more information.

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

The FDA stated its belief that additional modifications were needed for our study design to support marketing approval, and recommended, but did not require, that we modify our study to address the issues described above. Incorporating such modifications may be costly or not possible at this point in the ongoing clinical study or lead to delays in obtaining approval from the FDA, which may be significant and adversely and materially affect our ability to successfully commercialize our r-SNM System. Further, even if we make changes to the study design to address these considerations, the FDA may not approve our r-SNM System.

In addition to our anticipated submission of a PMA based on data from the IDE process, on January 9, 2018, we also submitted to the FDA a premarket approval application, which we refer to as the “literature-based PMA,” in which equivalence to an already FDA approved product is claimed based on the review of technical specifications, published clinical studies, and other information. In our filing, we are claiming equivalence to the only FDA approved SNM device, InterStim II. On May 9, 2018, the FDA responded and requested that we submit additional information to demonstrate that our r-SNM device is sufficiently similar to the InterStim II device referenced in the literature to be able to determine safety and effectiveness from the literature. The FDA’s response also asked us to address a number of other matters, including those related to the electrical safety, electromagnetic compatibility and wireless technology, biocompatibility, and our pre-clinical studies. On October 18, 2018, we responded to the FDA and voluntarily withdrew the literature-based PMA. Subsequent to further consultation with the FDA, which is pending, we will evaluate the merits of submitting a new literature-based PMA application, if at all.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our r-SNM System or impact our ability to modify or seek additional indications for our r-SNM System on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain approvals once obtained. For example, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, and the FDA Reauthorization Act, enacted in 2017, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several “Medical Device Regulatory Improvements” and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. Some of these proposals and reforms could

impose additional regulatory requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain approvals once obtained.

In order to sell our r-SNM System in member countries of the European Economic Area, or EEA (which is composed of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), it must comply with the essential requirements of the EU Active Implantable Medical Devices Directive (Council Directive 90/385/EEC), or the AIMD Directive. If any future product candidates are also considered to qualify as an active implantable medical device, or AIMD, under the AIMD Directive, it too will need to comply with the essential requirements it sets out. Alternatively, if a future product candidate is not considered an AIMD under the AIMD Directive, it will still be required to comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). The Medical Devices Regulations (Regulation 2017/745) are also now in force, as further discussed below.

Compliance with the requirements under either of these Directives and confirmation by a Notifiable Body that this is the case is a prerequisite to be able to affix the Conformité Européene, or CE, mark to our r-SNM System and any future product candidates. Without a CE mark, medical devices cannot be sold or marketed in the EEA. To demonstrate that our r-SNM System is compliant with the essential requirements set out under the AIMD Directive, we must undergo a conformity assessment procedure. This requires an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed to ensure and declare that the products in question comply with the standards set out in Annex I of the AIMD Directive. In addition, a conformity assessment procedure requires the intervention of a Notified Body. Notified Bodies are separate entities that are authorized or licensed to perform such assessments by the governmental authorities of each EU Member State. Manufacturers of AIMDs must make an application to a Notified Body for an assessment of its technical dossiers and quality system. Alternatively, manufacturers can seek approval from the Notified Body that a representative sample of the products it has manufactured satisfies the requirements set out in the AIMD Directive and subsequently ensure and declare that all of its products conform to the standard of the approved sample. This is also known as “type approval.”

Future product candidates that are not considered AIMDs under the AIMD Directive will still require a conformity assessment procedure. The types of procedures required are set out in the Medical Devices Directive and will vary according to the type of medical device and its classification. For low-risk medical devices (Class I non-sterile, non-measuring devices) the manufacturer can issue a Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive. However, for all other types of medical devices a similar conformity assessment procedure to that outlined above and in the AIMD Directive will be required, also involving the intervention of a Notified Body.

For our r-SNM System, future AIMD product candidates and all other future product candidates, the Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with the applicable Directives outlined above, we would be unable to continue to affix the CE mark to our r-SNM System or our external trial system, which would prevent us from selling it within the EEA.

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

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

The misuse or off-label use of our r-SNM System, if approved by the FDA, may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about approved medical devices, such as our r-SNM System, if approved by the FDA. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or other similar regulatory authorities as reflected in the product's approved labeling. If we receive approval for our r-SNM System in the United States for the treatment of UUI, physicians could use our r-SNM System on their patients in a manner that is inconsistent with the approved label, including the treatment of other indications. If approved, we will train our marketing personnel and sales representatives to not promote our r-SNM System for uses outside of FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our r-SNM System off-label when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our r-SNM System off-label. Furthermore, the use of our r-SNM System for indications other than those that may be approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. In addition, physicians have experience using the Medtronic system, which is approved for several indications, including UUI, UUF, FI, and UR. If physicians adopt our r-SNM System, for which we have not pursued regulatory approval in the United States for indications other than for the treatment of UUI, physicians could use our r-SNM System off-label for additional unapproved indications based in part on their familiarity with the Medtronic system.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of a warning letter, an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages (including treble damages), fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our r-SNM System or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to an increased risk of product liability claims. If our r-SNM System is approved, and subsequently misused or used with improper techniques or is determined to cause or contribute to patient harm, we may become subject to costly litigation by our customers or patients.

Product liability claims could divert management's attention from the commercialization of our r-SNM System, be expensive to defend, result in sizeable damage awards against us that may not be covered by insurance, and subject us to negative publicity resulting in reduced sales of our r-SNM System.

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

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

We completed enrollment of our ARTISAN-SNM pivotal study in June 2018 in support of our PMA for our r-SNM System. We expect to submit our PMA application to the FDA for UUI, a predominant OAB subtype, during the first quarter of 2019. If this study produces unfavorable results or the FDA requires additional data, we may have to conduct additional clinical studies, which would be costly and time-consuming, and our business would be adversely affected.

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

In response, we have engaged with the FDA regarding its recommendation, including our latest IDE supplement, which we submitted to the FDA in September 2018 to address certain of its recommendations. As a result, we incorporated a number of recommended study modifications. However, to date we elected not to incorporate several of the recommended modifications based on what we believe are currently accepted urology practice guidelines and the design of previous OAB clinical studies accepted by the FDA. We believe certain of these modifications would have resulted in a study design that increased study site and patient burdens, decreased the feasibility of enrollment or were not clearly supported by available peer-reviewed literature or currently accepted urology practice guidelines. At this point in the study, some of the FDA's recommendations cannot be implemented. For example, we cannot exclude patients with MUI and we cannot change the three-day bladder diaries taken at baseline to seven-day bladder diaries. On October 19, 2018, the FDA approved our latest IDE supplement and removed certain of its prior study design recommendations. However, the FDA also continues to reiterate several of its recommended study modifications, including exclusion of patients with MUI, use of a seven-day bladder diary or two separate three-day bladder diaries, use of a 12-month primary effectiveness endpoint and use of all patients in whom an implant is attempted, instead of initial responders after one month, for our primary efficacy analysis. See "Business—Our Clinical Results and Studies—ARTISAN-SNM Pivotal Study" for more information.

Although we have not modified the ARTISAN-SNM pivotal study design to address all of its reiterated considerations with the FDA, based on the preliminary study results to date, and assuming sufficiently strong

study results at six months and beyond, we believe we will be able to provide the FDA with reasonable assurance of the safety and effectiveness of our r-SNM system to support its marketing approval. However, it is possible that the results will not be sufficiently strong or that, in part due to its concerns with our study design, the FDA will not accept the data as reasonable assurance of safety and effectiveness, which would materially and adversely affect our ability to obtain marketing approval of our r-SNM System. If we intend to modify the study design to address those FDA considerations that we have not already addressed, we will be required to obtain FDA approval of an IDE supplement before implementing the changes, which could result in significant delays. The approval requirements for an IDE supplement are generally the same as an original IDE, and they are approved if the FDA does not object within 30 days. We would also be required to get IRB approval of the protocol changes if the changes involve the rights, safety, or welfare of the patients, and some investigators may determine that local rules require additional approvals from a local IRB.

In addition to our anticipated submission of a PMA based on data from the IDE process, on January 9, 2018, we also submitted to the FDA a premarket approval application, which we refer to as the "literature-based PMA," in which equivalence to an already FDA approved product is claimed based on the review of technical specifications, published clinical studies, and other information. In our filing, we are claiming equivalence to the only FDA approved SNM device, InterStim II. On May 9, 2018, the FDA responded and requested that we submit additional information to demonstrate that our r-SNM device is sufficiently similar to the InterStim II device referenced in the literature to be able to determine safety and effectiveness from the literature. The FDA's response also asked us to address a number of other matters, including those related to the electrical safety, electromagnetic compatibility and wireless technology, biocompatibility, and our pre-clinical studies. On October 18, 2018, we responded to the FDA and voluntarily withdrew the literature-based PMA. Subsequent to further consultation with the FDA, which is pending, we will evaluate the merits of submitting a new literature-based PMA application, if at all.

The FDA stated its belief that additional modifications were needed for our study design to support marketing approval, and recommended, but did not require, that we modify our study to address the issues previously described. Incorporating such modifications may be costly or not possible at this point in the ongoing clinical study or lead to delays in obtaining approval from the FDA, which may be significant and adversely and materially affect our ability to successfully commercialize our r-SNM System. Further, even if we make changes to the study design to address these considerations, the FDA may not approve our r-SNM System.

Successful results of pre-clinical studies are not necessarily indicative of future clinical study results, and predecessor clinical study results may not be replicated in subsequent clinical studies. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical studies, or may find the clinical study design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical studies, which could further delay the clearance or approval of our r-SNM System. The data we collect from our pre-clinical studies and clinical studies may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and effectiveness of our r-SNM System in our clinical studies, we will be unable to obtain regulatory clearance or approval to market our r-SNM System.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include obtaining the right to affix the CE mark to certain products in the EU, submitting an IDE to the FDA, applying to commence a pivotal clinical study for a new product, enrolling patients in clinical studies, releasing data from clinical studies, and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates and public announcements, in some cases for reasons beyond our control. We may not meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our r-SNM System may be delayed and, as a result, our stock price may decline.

Clinical studies are necessary to support PMA applications and may be necessary to support PMA supplements for modified versions of, or additional indications for, our r-SNM System. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. Adverse outcomes in the post-approval studies could also result in restrictions or withdrawal of approval of a PMA. We will likely need to conduct additional clinical studies in the future to support new indications for our r-SNM System or for approvals or clearances, or for the approval of the use of our r-SNM System in some foreign countries. Clinical testing is difficult to design and implement, can take many years, can be expensive, and, testing carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. We may experience a number of events that could adversely affect the costs, timing or successful completion of our clinical studies, including:

- we may be required to submit an IDE application to FDA, which must become effective prior to commencing human clinical studies, and the FDA may reject our IDE application and notify us that we may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies;
- regulators and/or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical study at a prospective or specific trial site;
- we may not reach agreements with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- our third-party manufacturers, including those conducting clinical studies on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical study protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical studies may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;

- we may be unable to recruit a sufficient number of clinical study sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers or suppliers of materials for our clinical studies, the materials necessary to conduct clinical studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our r-SNM System may have undesirable side effects or other unexpected characteristics.

Patient enrollment in clinical studies and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical studies if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of a product, or they may be persuaded to participate in contemporaneous clinical studies of a competitor's product. In addition, patients participating in our clinical studies may drop out before completion of the trial or experience adverse medical events unrelated to our r-SNM System. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial, or result in the failure of the clinical trial.

Clinical studies must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with supplies of our product produced under cGMP requirements and other regulations. Furthermore, we rely on clinical study sites to ensure the proper and timely conduct of our clinical studies and we have limited influence over their performance. We depend on our collaborators and on medical institutions and employees to conduct our clinical studies in compliance with good clinical practice, or GCP, requirements. If our collaborators fail to enroll participants for our clinical studies, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical studies that are conducted in countries outside the United States may result in additional delays and expenses due to increased shipment costs, additional regulatory requirements and the engagement of non-U.S. resources, and may expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned. Our failure to adequately demonstrate the safety and effectiveness of our r-SNM System or any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of the product or indication for use. Even if our r-SNM System is cleared or approved in the United States, commercialization of our r-SNM System in foreign countries requires approval by regulatory authorities in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical studies. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

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

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

In addition, in order to obtain PMA approval for our r-SNM System, we may be to subject to several conditions of approval, including a post-market long-term study and extended follow-up of the pre-market study cohort. Any failure to comply with the conditions of approval could result in the failure to obtain PMA approval or delay or withdrawal of PMA approval and the inability to market the device. Failure to conduct the required studies in accordance with IRB and informed consent requirements, or adverse findings in these studies, could also be grounds for failure to obtain PMA approval or delay or withdrawal of PMA approval.

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

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our r-SNM System;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our request for PMA approval of our r-SNM System and any future PMA approvals or foreign regulatory approvals of future product candidates, new intended uses, or modifications to our existing product;
- withdrawals or suspensions of PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our r-SNM System;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

Our r-SNM System must be manufactured in accordance with federal and state regulations, and we or any of our suppliers or third-party manufacturers could be forced to recall our r-SNM System or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our r-SNM System must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our r-SNM System will also be subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our r-SNM System, if approved. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with the manufacturing processes for our r-SNM System could result in, among other things: warning letters or untitled letters, fines, injunctions or civil penalties, suspension or withdrawal of approvals, seizures or recalls of our r-SNM System, total or partial suspension of production or distribution, administrative or judicially imposed sanctions, the FDA's refusal to grant pending or future clearances or approvals for our product, clinical holds, refusal to permit the import or export of our r-SNM System, and criminal prosecution of us or our employees. Any of these actions could significantly and negatively affect supply of our r-SNM System. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

If our r-SNM System is approved by the FDA and treatment guidelines for OAB subtype UUI later change or the standard of care evolves, we may need to redesign and seek new a marketing authorization from the FDA for our r-SNM System.

If our r-SNM System is approved by the FDA for OAB subtype UUI and treatment guidelines for UUI change or the standard of care evolves, we may need to redesign our r-SNM System, or any future product, and seek new approvals from the FDA. PMA approvals from the FDA are based on current treatment guidelines at the time of the approvals. If treatment guidelines change so that different treatments become desirable, the clinical utility of our r-SNM System could be diminished and our business could be adversely affected.

If approved, our r-SNM System may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our r-SNM System, or a recall of our r-SNM System, either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

If our r-SNM System is approved by the FDA, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which will require us to report to the FDA when we receive or become aware of information that reasonably suggests that our r-SNM System may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal

prosecution, imposition of civil monetary penalties, revocation of device approvals, seizure of our r-SNM System or delay in clearance or approval of modifications to our r-SNM System.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that our r-SNM System could cause serious injury or death. We may also choose to voluntarily recall our r-SNM System if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Defects or other errors in our r-SNM System may occur in the future. Depending on the corrective action we take to redress deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals for our r-SNM System before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our r-SNM System, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our r-SNM System in the future that we may determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our r-SNM System after obtaining regulatory approval in the United States or other jurisdictions, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or issuance of field alerts to physicians and pharmacies;
- regulatory authorities may require us to create a guide outlining the risks of such side effects for distribution to patients;
- we may be subject to limitations as to how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way;
- regulatory authorities may require additional clinical studies or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;

- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events could prevent us from achieving or maintaining market acceptance of our r-SNM System and could substantially increase the costs of commercializing our r-SNM System. The demand for our r-SNM System could also be negatively impacted by any adverse effects of a competitor's product or treatment.

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

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

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

Legislative or regulatory reforms in the United States or Europe may make it more difficult and costly for us to obtain regulatory clearances or approvals for our r-SNM System, or to manufacture, market or distribute our r-SNM System after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in U.S. Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our r-SNM System. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of or make it more difficult to obtain approval for, manufacture, market or distribute our r-SNM System. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval for future product candidates, changes to manufacturing methods, recall, replacement or discontinuance of future product candidates, or additional record keeping.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. The Medical Devices Regulations would be directly applicable and are intended to eliminate

current differences in the regulation of medical devices among EEA member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

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

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

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

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

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

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $74,792 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the

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

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH Act, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state;

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the EU General Data Protection Regulation, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and

- state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our r-SNM System. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to

a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and responding to any such challenge or investigation would be costly and divert the attention of our management. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations.

We may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, store and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

As described above, in the conduct of our business, we may at times process personal data, including health-related personal data. The U.S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U.S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. State privacy and security laws vary from state to state and, in some cases, can impose more restrictive requirements than U.S. federal law. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for misuse of personal information.

The EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, which are often more restrictive than those in the United States and which restrict transfers of personal data to the United States unless certain requirements are met. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme was declared invalid. In July 2016 the European Commission adopted the U.S.-EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this framework is under review and there is currently litigation challenging other EU mechanisms for adequate data transfers (i.e., the standard contractual clauses). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our EU business to the U.S., and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the EU General Data Protection Regulation 2016/679, or the GDPR, which came into effect on May 25, 2018, as well as current challenges to these mechanisms in the European courts.

Any actual or perceived failure by us or the third parties with whom we work to comply with privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of personally identifiable information, may result in governmental enforcement actions and investigations including by European Data Protection Authorities and U.S. federal and state regulatory authorities, fines and penalties, litigation and/or adverse publicity, including by consumer advocacy groups, and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

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

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

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

In addition, applicable FCC requirements will restrict us to a particular band of frequencies for transmitting data in support of specific diagnostic or therapeutic functions. Failure to comply with all applicable restrictions on the use of such frequencies, or unforeseeable difficulties with the use of such frequencies, could impede our ability to commercialize our r-SNM System and could subject us to fines, penalties and other sanctions. In addition, any change to our transmission frequency following receipt of FCC approval may require us to obtain additional, or modified, regulatory approvals, which would be costly and time-consuming.

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

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

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

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

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

- expanded the eligibility criteria for Medicaid programs.

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

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

Our business involves the use of hazardous materials and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.

Our third-party manufacturers' activities may involve the controlled storage, use and disposal of hazardous materials. Our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe the safety procedures of our manufacturers for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our manufacturers' use of these materials and interrupt their business operations which could adversely affect our business.

Compliance with securities rules relating to "conflict minerals" may require us and our suppliers to incur substantial expense and may result in disclosure by us that certain minerals used in products we manufacture or contract to manufacture are not "DRC conflict free."

Because we manufacture or contract to manufacture a product that contains titanium, we may be required under rules promulgated by the SEC governing disclosure of the use of "conflict minerals" (tin, tungsten, tantalum and gold) to determine whether those minerals are necessary to the functionality or production of our r-SNM System and, if so, conduct a country of origin inquiry with respect to all such minerals. If any such minerals may have originated in the Democratic Republic of the Congo, or DRC, or any of its adjoining countries, or covered countries, then we must conduct diligence on the source and chain of custody of those conflict minerals to determine if they originated in one of the covered countries and, if so, whether they financed or benefited armed groups in the covered countries. Disclosures relating to the products that may contain conflict minerals, the country of origin of those minerals and whether they are "DRC conflict free" must be provided in a

Form SD (and accompanying conflict minerals report, if required, to disclose the diligence undertaken by us in sourcing the minerals and our conclusions relating to such diligence). If we are required to submit a conflict minerals report, that report must be audited by an independent auditor pursuant to existing government auditing standards. Compliance with this disclosure rule may be very time-consuming for our management and personnel (as well as time-consuming for our suppliers) and could involve the expenditure of significant amounts of money by us and them. Disclosures mandated by this rule, which can be perceived by the market to be "negative," may cause customers to refuse to purchase our r-SNM System. The cost of compliance with the rule could adversely affect our results of operations.

Risks Related to Intellectual Property

If we or any of our current or future licensors, including AMF, are unable to maintain, obtain or adequately protect our intellectual property rights, we may not be able to compete effectively in our market or we could be required to incur significant expenses to enforce or defend our rights or attempt to do the same.

Our commercial success depends in part on ours and any of our current or future licensors', including AMF's, success in obtaining, maintaining and protecting patents, trademarks, trade secrets and other intellectual property rights and proprietary technology in the United States and elsewhere. If we or any of our current or future licensors, including AMF, do not adequately protect our respective intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Our intellectual property coverage includes protection provided by patents and other intellectual property licensed through the License Agreement with AMF. We rely on AMF to maintain the patents and otherwise protect the intellectual property we license from them. If in the future we no longer have rights to one or more of these licensed patents or other licensed intellectual property, our intellectual property coverage may be compromised, which in turn could affect our ability to protect our r-SNM System and defend it against competitors.

We own numerous issued patents and pending patent applications that relate to our r-SNM System and several issued patents and patent applications were licensed from AMF in 2013 pursuant to the License Agreement. As of September 30, 2018, we owned 17 issued U.S. patents and 20 issued foreign patents, and 17 pending U.S. patent applications and 59 pending foreign patent applications, and we licensed from AMF 30 issued U.S. patents and 38 issued foreign patents, and four pending U.S. patent applications and 28 pending foreign patent applications.

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:

- any of our patents, or any of 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, if approved, before our relevant patents have expired;
- we were the first to make, or file for patent protection of, the inventions covered by each of our patents and pending patent applications, as is dictated by the applicable national patent laws in effect at the time of a patent application being filed;
- we were the first to file patent applications for these inventions, where such rules are applicable;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

In addition, we rely in part upon unpatented trade secrets, unpatented know-how, and continuing technological innovation which may not yet, or may never be, patented, to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and consultants. We also have agreements with our employees and consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. In addition, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Further, our trade secrets could otherwise become known or be independently discovered by our competitors, which would harm our business.

We are reliant on the ability of AMF, as licensor of certain intellectual property contained in our r-SNM System, and may be reliant on, future licensors to maintain their intellectual property and protect their intellectual property against misappropriation, infringement or other violation. In some instances, we may not have primary control over AMF's, or our other future licensors', patent prosecution activities. With respect to licensed patents that were issued to our licensors, or patents that may issue on patent applications, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. As a licensee, we are reliant on AMF to defend any third-party claims or consent to our defending them on their behalf. Our licensors may not defend or prosecute such actions as vigorously or in the manner that we would have if entitled to do so, and we will be subject to any judgment or settlement resulting from such actions and our business could be adversely affected.

Litigation or other proceedings or third-party claims of intellectual property infringement against us or any of our current or future licensors, including AMF, could require us to spend significant time and money and could prevent us from selling our r-SNM System, or affect our stock price.

Our commercial success will depend in part on our ability to avoid infringement of the proprietary rights of third parties. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Our competitors in both the United States and internationally, many of which have substantially greater resources, and, may have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our r-SNM System. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications for other patents now pending or recently revived patents of which we are unaware that our r-SNM System may infringe. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the technology and medical device industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination or review proceedings before the U.S. Patent and Trademark Office. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our r-SNM System or will develop future product candidates. As the technology and medical device industries expand and more patents are issued, the risk continues, or possibly increases, that our r-SNM System may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we, or any of our current or future licensors, including AMF, are employing their proprietary technology without authorization. If any third-party patents were held by a court of competent jurisdiction to cover our r-SNM System, the holders of any such patents may be able to block our

ability to commercialize our product unless we obtain a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

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

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

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

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

Any litigation or claim against us or AMF, even those without merit, may cause us to incur substantial costs, and, could place a significant strain on our financial resources, divert the attention of management from commercialization of our r-SNM System, or harm our reputation. If we or AMF are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our infringing products unless we obtain a license or are able to redesign our r-SNM System to avoid infringement. Any such license may not be available on reasonable terms, if at all, and we may not be able to redesign the infringing product in a way that would not infringe the intellectual property rights of others. We

could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses, or make any necessary changes to our r-SNM System, including future technologies, we may have to withdraw our r-SNM System from the market or may be unable to commercialize our r-SNM System.

In addition, third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or indemnify our customers for any costs associated with their own initiation or defense of infringement claims, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our r-SNM System.

If we are unable to protect the confidentiality of our trade secrets, our business or competitive position could be harmed.

In addition to patent protection, we also rely upon other non-patent protection, such as: trademark, or, trade secret protection, as well as confidentiality agreements with our employees, consultants, vendors, and third parties, to protect our confidential and proprietary information. Despite the existence of such confidentiality agreements, or other contractual restrictions, we may not be able to prevent the unauthorized disclosure or use of our confidential proprietary information or trade secrets by employees, consultants, vendors, and third parties. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and, recourse we take against such misconduct may not provide an adequate remedy to fully protect our interests. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our r-SNM System that we consider proprietary. Enforcing a claim that a party illegally disclosed, or misappropriated a trade secret, can be difficult, expensive and time-consuming, and, the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. Furthermore, the laws of foreign countries may not protect our trade secrets effectively or to the same extent as the laws of the United States. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. If we face similar challenges in respect of 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 develop or market our r-SNM System. In addition, any claims asserted against us by AMF may be costly and time-consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business.

Risks Related to this Offering and Our Common Stock

There has been no prior public market for our common stock and an active trading market may never develop or be sustained.

Prior to this offering, there has been no public market for our common stock. An active trading market for our shares may never develop or be sustained following this offering. If an active trading market for our common stock does not develop, it may be difficult for you to sell the shares that you purchase in this offering without depressing the market price for the common stock or to sell your shares at all. The initial public offering price for our common stock will be determined through negotiations between us and the underwriters, and may bear no relationship to the price at which the common stock will trade upon the closing of this offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. In addition, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The trading price of our common stock is likely to be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to 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. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price and may not realize any return on their investment. The market price for our common stock may be influenced by many factors, some of which are beyond our control, including:

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

- any voluntary or regulatory mandated product recalls;
- adverse developments concerning our manufacturers or suppliers or any future strategic partnerships;
- introductions and announcements of new technologies by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- success or failure of competitive products or therapies in the SNM market;
- changes in the structure of healthcare payment of our r-SNM System;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the medical technology industry and issuance of securities analysts' reports or recommendations;
- quarterly variations in our results of operations or those of our future competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- the public's reaction to our earnings releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- sales of substantial amounts of our stock by directors, officers or significant stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions, including the size and growth, if any, of the market;
- news reports relating to trends, concerns and other issues in the market or industry;
- operating and stock performance of other companies that investors deem comparable to us and overall performance of the equity markets;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us, our third-party manufacturers or other parties on which we rely or litigation against our general industry;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt;
- changes in accounting standards, policies, guidelines, interpretations or principles; and
- other factors described in this "Risk Factors" section.

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

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we remain an emerging growth company, we may take advantage of certain exemptions and relief 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;
- 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.

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 elected to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, and our consolidated financial statements may not be directly comparable to other public companies.

Pursuant to the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies.

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

Based on the beneficial ownership of our common stock as of June 30, 2018, following this offering, our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, will control approximately 62.3% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The

interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of our company, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders. Certain of our existing stockholders that are affiliated with certain of our directors have indicated an interest in purchasing an aggregate of up to approximately $45.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering. The foregoing discussion does not give effect to any potential purchases by these stockholders in this offering.

Because the initial public offering price of our common stock will be substantially higher than the pro forma net tangible book value per share of our outstanding common stock following this offering, new investors will experience immediate and substantial dilution.

The initial public offering price will be substantially higher than the pro forma net tangible book value per share of our common stock immediately following 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 $10.17 per share, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma as adjusted net tangible book value per share as of June 30, 2018. To the extent outstanding stock options or warrants to purchase shares of our common stock are exercised, new investors may incur further dilution.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that these sales may occur, could result in a decrease in the market price of our common stock. Immediately after this offering, we will have outstanding 25,305,600 shares of common stock, based on the number of shares common stock outstanding as of June 30, 2018, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into shares of our common stock immediately prior to the closing of this offering. 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 or existing stockholders. Of the remaining shares, 18,576,632 shares are currently restricted as a result of securities laws or 180-day lock-up agreements (which may be waived with or without notice by Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC) but will be able to be sold beginning 180 days after this offering, unless held by one of our affiliates, in which case the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended, or the Securities Act. We, our directors, executive officers, and substantially all of our other existing equityholders have agreed that, without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC, we and they will not, subject to certain exceptions and extensions, during the period ending 180-days after the date of this prospectus, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock or publicly disclose the intention to do any of the foregoing. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC may in their discretion and at any time without notice release all or any portion of the shares of our common stock subject to the lock-up.

In addition, following this offering, holders of an aggregate of up to 16,701,297 shares of our common stock, including shares of our common stock issuable upon the conversion of the shares of our preferred stock immediately prior to the closing of this offering, will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders as described in the section entitled "Description of Capital Stock—Registration Rights." In addition, we intend to file one or more registration statements with the SEC covering shares of our common stock available for future issuance under the 2014 Plan, 2018 Plan and any future equity incentive plans. Upon effectiveness of such registration statements, any shares subsequently issued under such plans will be eligible for sale in the public market, except to the extent that they are restricted by the lock-up agreements referred to above and subject to compliance with Rule 144 in the case of our affiliates. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of our common stock.

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 as follows: (i) approximately $30.0 million to hire sales and clinical support personnel, including a specialty sales force of approximately 60 sales representatives, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval, to support the commercial launch of our r-SNM System in the United States, and to fund marketing initiatives in United States, Europe and Canada, (ii) approximately $25.0 million to conduct SNM-related research and development activities, consisting of expanding the suite of product solutions available for SNM therapy over time and to fund the technological enhancement of our r-SNM System, including, but not limited to, 1.5T/3.0T MRI full body conditional labelling for our r-SNM System, a reduction by half in the number of IPG battery recharging sessions required for the IPG to remain charged for one full month, and features that would enable us to connect our IPG to an already implanted InterStim II lead, and (iii) the remainder 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.

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

Upon completion of this offering, we expect to incur significant costs associated with corporate governance requirements that will become 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 the Nasdaq Global Market, or 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.

As a result of becoming a public company, we will be obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in us, and, as a result, the value of our common stock.

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

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

We have identified material weaknesses in our internal control over financial reporting, which resulted in the restatement of our consolidated financial statements. If we do not remediate the material weaknesses in our internal control over financial reporting, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the audits of our financial statements for the years ended December 31, 2017 and 2016, we concluded that there were material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to the accounting and reporting of complex financial instruments and consolidation matters, which resulted in the restatement of our consolidated financial statements for the years ended December 31, 2016 and 2017 and for the six-months ended June 30, 2018 as further described in Note 10 to our consolidated financial statements included elsewhere in this prospectus. A lack of adequate staffing levels resulted in insufficient time spent on review and approval of certain information used to prepare our consolidated financial statements and the maintenance of effective controls to adequately monitor and review significant transactions for financial statement completeness and accuracy.

We are taking steps to remediate the material weaknesses in our internal control over financial reporting, including engaging in a review of our processes and procedures, enhancing training of our personnel,

implementing new accounting processes and control procedures and identifying gaps in our skills base and expertise of the staff required to meet the financial reporting requirements of a public company. We plan to hire additional accounting personnel who are certified public accountants, which will enable us to better address the accounting for complex financial instruments or consolidation matters or other complex accounting matters that may occur in the future. Although we plan to complete the above remediation process and associated evaluation and testing as quickly as possible, we may not be able to do so and our initiatives may prove not to be successful. Our remediation efforts may not remediate our material weaknesses in a timely manner, or at all, or prevent restatements of our financial statements in the future. If we are unable to successfully remediate our material weaknesses, or identify any future significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, and the market price of our common stock may decline as a result.

Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of Sarbanes-Oxley Act, additional control deficiencies amounting to material weaknesses may have been identified. As a result of becoming a public company, we will be required, under Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2019. We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404(a) of Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. If we fail to comply with Section 404(a) or to remedy these material weaknesses or identify new material weaknesses by the time we have to issue that report, we will not be able to certify that our internal controls over financial reporting are effective, which may cause investors to lose confidence in our financial statements, and the trading price of our common stock may decline. If we fail to remedy any material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our common stock may suffer.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. 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 that will become effective upon the completion of this offering 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 that will become effective upon the completion of this offering provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws or any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein and the claim not being one which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or for which the Court of Chancery does not have subject matter jurisdiction. In addition, unless we consent in writing to the selection of an alternative forum, the U.S. District Court for the District of Delaware shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our certificate of incorporation. This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

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

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

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.

If a trading market for our common stock develops, the trading market will depend in part on the research and reports that securities or industry analysts publish about us and our business. We do not currently have and may never obtain research coverage by securities and industry analysts. As a newly public company, we may be slow to attract research coverage and the analysts who publish information about our common stock will have had relatively little experience with us or our industry, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. Analysts may elect not to provide research coverage of our common stock after the closing of this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we obtain analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more analysts downgrade our common stock or issue inaccurate or unfavorable commentary or research about our business. If one or more analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common 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.

FORWARD-LOOKING STATEMENTS AND STATISTICAL DATA

Special Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements that involve risks and uncertainties, including statements based on our current expectations, assumptions, estimates and projections about future events, our business, financial condition, results of operations and prospects, our industry and the regulatory environment in which we operate. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, or other comparable terms intended to identify statements about the future. Forward-looking statements include, but are not limited to, statements about:

- our ability to obtain and maintain regulatory approvals of our r-SNM System;
- our ability to successfully commercialize our r-SNM System in the United States, if approved, 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 and expand what our r-SNM System is indicated for;
- 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;
- 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; 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. 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 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.

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 and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement on Form S-1, 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 estimate that we will receive net proceeds of approximately $90.7 million (or approximately $104.6 million if the underwriters' option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $6.2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us by $14.0 million, assuming the shares of our common stock offered by this prospectus are sold at the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to fund the commercial launch of our r-SNM System in the United States, if approved by the FDA. We intend to use the net proceeds from this offering as follows:

- approximately $30.0 million to hire sales and clinical support personnel, including a specialty sales force of approximately 60 sales representatives, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval, to support the commercial launch of our r-SNM System in the United States, and to fund marketing initiatives in United States, Europe and Canada;

- approximately $25.0 million to conduct SNM-related research and development activities, consisting of expanding the suite of product solutions available for SNM therapy over time and to fund the technological enhancement of our r-SNM System, including, but not limited to, 1.5T/3.0T MRI full body conditional labelling for our r-SNM System, a reduction by half in the number of IPG battery recharging sessions required for the IPG to remain charged for one full month, and features that would enable us to connect our IPG to an already implanted InterStim II lead; and

- the remainder for working capital and general corporate purposes.

As of the date of this prospectus, 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.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our capital stock for the foreseeable future. We intend to retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, pursuant to the Loan Agreement with Silicon Valley Bank, we are prohibited from paying cash dividends without the prior written consent of Silicon Valley Bank and future debt instruments may materially restrict our ability to pay dividends on our common stock. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, tax considerations, legal or contractual restrictions, business prospects, the requirements of current or then-existing debt instruments, general economic conditions and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and capitalization as of June 30, 2018:

- on an actual basis;
- on a pro forma basis to give effect to: (i) the automatic exchange of the exchanged preferred stock immediately prior to the completion of this offering, (ii) the automatic conversion of all outstanding shares of our preferred stock, including the exchanged preferred stock, into 15,813,297 shares of our common stock upon completion of this offering, (iii) the automatic conversion of outstanding warrants to purchase shares of our Series C preferred stock into warrants to purchase 40,001 shares of our common stock in connection with the completion of this offering, and the resulting reclassification of such warrants from a current liability to stockholders' equity (deficit), and (iv) the filing and effectiveness of our certificate of incorporation, which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 6,667,000 shares of common stock in this offering at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only and our capitalization following the completion of this offering is subject to adjustment based on the initial public offering price of our common stock and other terms of this offering determined at pricing. You should read the following table in conjunction with "Use of Proceeds," "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and other financial information contained in this prospectus, including the consolidated financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2018		
	Actual(1) (unaudited, restated)	Pro Forma (unaudited)	Pro Forma As Adjusted(2) (unaudited)
	(in thousands, except share and per share data)		
Cash, cash equivalents and short-term investments	$ 39,881	$ 39,881	$ 130,547
Debt, net(3)	$ 8,985	$ 8,985	$ 8,985
Mezzanine equity:			
Series A Convertible Preferred Stock, par value $0.0001 per share, 1,030,000 shares authorized, 719,500 shares issued and outstanding, actual, no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	14,021	—	—
Series B-1 Convertible Preferred Stock, par value $0.0001 per share, 2,529,862 shares authorized, 1,925,302 shares issued and outstanding, actual, no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	13,757	—	—
Series B-2 Convertible Preferred Stock, par value $0.0001 per share, 2,537,231 shares authorized, 2,213,794 shares issued and outstanding, actual, no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	17,572	—	—
Series C Convertible Preferred Stock, par value $0.0001 per share, 6,188,888 shares authorized, 4,131,546 shares issued and outstanding, actual, no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	36,776	—	—
Noncontrolling interest in Axonics Europe S.A.S.	31,066	—	—
Stockholders' equity (deficit):			
Common Stock, par value $0.0001 per share, 17,500,000 shares authorized, 2,825,303 shares issued and outstanding, actual; 50,000,000 shares authorized, 18,638,600 shares issued and outstanding, pro forma; 50,000,000 shares authorized, 25,305,600 shares issued and outstanding, pro forma as adjusted	0	2	3
Preferred Stock, par value $0.0001 per share; no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Additional paid-in capital	3,230	116,661	207,326
Stock subscription receivable(4)	(1,824)	(1,824)	(1,824)
Accumulated deficit	(82,418)	(82,418)	(82,418)
Accumulated other comprehensive loss	(406)	(406)	(406)
Total stockholders' equity (deficit)	(81,418)	32,015	122,681
Total capitalization	$ 40,759	$ 41,000	$ 131,666

(1) See Note 10 to our consolidated financial statements appearing elsewhere in this prospectus for more information on the restatements of certain of our financial statements.

(2) Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and short-term investments, total assets and total stockholders' equity (deficit) by approximately $6.2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price, as set forth on the cover page of this prospectus, would increase (decrease) each of cash, cash equivalents and short-term investments, total assets and total stockholders' equity (deficit) by approximately $14.0 million, assuming the shares of our common stock offered by this prospectus are sold at the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Represents gross proceeds from the Term Loan of $10.0 million, net of unamortized debt issuance costs of $1,015,098. Does not reflect (i) $10.0 million in additional borrowings we requested under the Loan Agreement in October 2018, which we expect to receive prior to the closing of this offering, and (ii) the related concurrent issuance of warrants to purchase shares of our Series C preferred stock, which will become exercisable for 39,999 shares of our common stock immediately prior to the closing of this offering at an exercise price of $7.50 per share.

(4) Includes outstanding promissory notes as of June 30, 2018, with an aggregate principal balance of $1,782,268.70, that were issued to us by certain of our executive officers and directors in exchange for the exercise of an aggregate of 1,653,196 shares of common stock pursuant to stock option awards. We have entered into debt forgiveness and cancellation of note agreements with certain of our executive officers and directors, including each of our named executive officers, to terminate each of their respective promissory notes and to forgive all respective obligations for payment thereof in connection with this offering. See "Certain Relationships and Related Party Transactions—Loans to Officers and Directors."

The number of shares of common stock shown as issued and outstanding in the table excludes, as of June 30, 2018:

- 1,425,316 shares of our common stock issuable upon the exercise of outstanding stock options under the 2014 Plan, at a weighted-average exercise price of $1.35 per share;
- 37,971 shares of our common stock reserved for future issuance under the 2014 Plan;
- 4,540,019 shares of our common stock reserved for future issuance under the 2018 Plan, which became effective in October 2018; and
- 40,001 shares of our common stock issuable upon the exercise of outstanding warrants to purchase shares of our Series C preferred stock, which will convert into warrants to purchase 40,001 shares of our common stock in connection with the closing of this offering, at an exercise price of $7.50 per share.

In addition, the number of shares of our common stock after this offering does not give effect to 39,999 shares of our common stock issuable upon exercise of warrants to purchase shares of our Series C preferred stock, which will convert into warrants to purchase 39,999 shares of our common stock in connection with the completion of this offering, at an exercise price of $7.50 per share, that will become exercisable when we borrow an additional $10.0 million under the Loan Agreement with Silicon Valley Bank. As of the date of this prospectus, we have requested to borrow the additional $10.0 million and we expect to receive it prior to the completion of this offering.

The number of shares of preferred stock shown as issued and outstanding in the table excludes, as of June 30, 2018:

- 310,500 shares of our Series A preferred stock issuable upon the exchange of shares of Axonics Europe, which will automatically occur immediately prior to the completion of this offering in accordance with the Share Exchange Agreement;
- 604,560 shares of our Series B-1 preferred stock issuable upon the exchange of shares of Axonics Europe, which will automatically occur immediately prior to the completion of this offering in accordance with the Share Exchange Agreement;
- 323,437 shares of our Series B-2 preferred stock issuable upon the exchange of shares of Axonics Europe, which will automatically occur immediately prior to the completion of this offering in accordance with the Share Exchange Agreement; and
- 1,990,676 shares of our Series C preferred stock issuable upon the exchange of shares of Axonics Europe, which will automatically occur immediately prior to the completion of this offering in accordance with the Share Exchange Agreement.

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 initial public offering price per share and the pro forma 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 June 30, 2018. Our historical net tangible book value as of June 30, 2018 was approximately $31.29 million or $11.08 per share of common stock.

Our pro forma net tangible book value as of June 30, 2018 was $31.53 million, or $1.69 per share of common stock. Pro forma net tangible book value per share represents our net tangible book value divided by the number of shares of our common stock outstanding as of June 30, 2018, after giving effect to (i) the automatic exchange of the exchanged preferred stock immediately prior to the completion of this offering, (ii) the automatic conversion of all outstanding shares of our preferred stock, including the exchanged preferred stock, into 15,813,297 shares of our common stock upon completion of this offering, and (iii) the automatic conversion of outstanding warrants to purchase shares of our Series C preferred stock into warrants to purchase 40,001 shares of our common stock in connection with the completion of this offering, and the resulting reclassification of such warrants from a current liability to stockholders' equity (deficit).

After giving further effect to our sale of 6,667,000 shares of our common stock in this offering at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2018 would have been approximately $122.20 million, or approximately $4.83 per share. This amount represents an immediate increase in pro forma net tangible book value of $3.14 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $10.17 per share to new investors purchasing shares of our common stock in this offering. We determine dilution by subtracting our pro forma 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 this dilution:

Assumed initial public offering price per share		$15.00
Historical net tangible book value per share as of June 30, 2018	$11.08	
Decrease in pro forma net tangible book value	(9.39)	
Pro forma net tangible book value per share as of June 30, 2018, before giving effect to this offering	1.69	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	3.14	
Pro forma as adjusted net tangible book value per share after this offering		4.83
Dilution in pro forma net tangible book value per share to investors purchasing in this offering		$10.17

Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately $0.25 per share and the dilution in pro forma net tangible book value (deficit) per share to investors purchasing in this offering by approximately $0.75 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a 1.0 million share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net

tangible book value (deficit) per share after this offering by approximately $0.35 and decrease the dilution in pro forma net tangible book value (deficit) per share to investors purchasing in this offering by approximately $0.35, assuming the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A 1.0 million share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value (deficit) per share after this offering by $0.38 and increase the dilution in pro forma net tangible book value (deficit) per share to investors purchasing in this offering by approximately $0.38 per share, assuming the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase 1,000,050 additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value per share after this offering would be $5.18, the increase in pro forma net tangible book value per share attributable to new investors would be $3.49 and the dilution per share to new investors would be $9.82, in each case assuming an initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, as of June 30, 2018, on the pro forma as adjusted basis described above, the difference between our existing stockholders and the investors purchasing in this offering with respect to the number of shares of common stock purchased from us, the total consideration paid to us and the average price paid per share paid to us, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration (in thousands)		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	18,638,600	73.65%	$114,247	53.32%	$ 6.13
New investors	6,667,000	26.35%	$100,005	46.68%	$ 15.00
Total	25,305,600	100.00%	$214,252	100.00%	

In addition, the following table summarizes, as of June 30, 2018, on the pro forma as adjusted basis described above, the difference between our existing stockholders (assuming all of the options and warrants outstanding as of June 30, 2018 described below are exercised) and the investors purchasing in this offering with respect to the number of shares of common stock purchased from us, the total consideration paid to us and the average price paid per share paid to us, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration (in thousands)		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	20,103,917	75.10%	$116,466	53.80%	$ 5.79
New investors	6,667,000	24.90%	$100,005	46.20%	$ 15.00
Total	26,770,917	100.00%	$216,471	100.00%	

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price, the number of shares we sell and other terms of this offering that will be determined at pricing.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the total consideration paid by new investors and the average price per share paid by new investors would be approximately

$115.0 million and $15.00 per share, respectively, in each case assuming an initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors and the average price per share paid by new investors by $6.67 million and $1.00 per share, respectively. An increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) the total consideration paid by new investors by $15.00 million.

To the extent any of the outstanding options or warrants described below are exercised, new options are issued or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering. If all of the outstanding options and warrants described below were exercised, our pro forma net tangible book value at June 30, 2018, before giving effect to the issuance and sale of shares of our common stock in this offering, would have been approximately $33.75 million, or $1.68 per share of common stock. After giving further effect to our sale of 6,667,000 shares of our common stock in this offering at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2018 would have been approximately $124.42 million, or approximately $4.65 per share, causing dilution to new investors of approximately $10.35 per share.

The foregoing tables are based on the number of shares of our common stock outstanding as of June 30, 2018, after giving effect to the conversion of all of our outstanding shares of preferred stock, and exclude:

- 1,425,316 shares of our common stock issuable upon the exercise of outstanding stock options under the 2014 Plan, at a weighted-average exercise price of $1.35 per share;
- 37,971 shares of our common stock reserved for future issuance under the 2014 Plan;
- 4,540,019 shares of our common stock reserved for future issuance under the 2018 Plan, which became effective in October 2018; and
- 40,001 shares of our common stock issuable upon the exercise of outstanding warrants to purchase shares of our Series C preferred stock, which will convert into warrants to purchase 40,001 shares of our common stock in connection with the closing of this offering, at an exercise price of $7.50 per share.

In addition, the number of shares of our common stock after this offering does not give effect to 39,999 shares of our common stock issuable upon exercise of warrants to purchase shares of our Series C preferred stock, which will convert into warrants to purchase 39,999 shares of our common stock in connection with the completion of this offering, at an exercise price of $7.50 per share, that will become exercisable when we borrow an additional $10.0 million under the Loan Agreement with Silicon Valley Bank. As of the date of this prospectus, we have requested to borrow the additional $10.0 million and we expect to receive it prior to the completion of 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 any outstanding stock options are exercised, new stock options are issued under the 2014 Plan or 2018 Plan, or 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.

Certain of our existing stockholders that are affiliated with certain of our directors have indicated an interest in purchasing an aggregate of up to approximately $45.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering. The foregoing discussion does not give effect to any potential purchases by these stockholders in this offering.

SELECTED FINANCIAL DATA

The following tables contain selected portions of our financial data. We derived our selected consolidated statements of comprehensive loss for the years ended December 31, 2016 and 2017, and our selected consolidated balance sheets data as of December 31, 2016 and 2017, from our audited consolidated financial statements and related notes included elsewhere in this prospectus. We derived our selected consolidated statements of comprehensive loss for the six months ended June 30, 2017 and 2018, and our selected consolidated balance sheets data as of June 30, 2018, from our unaudited interim consolidated financial statements that are included elsewhere in this prospectus. We have prepared this unaudited information on the same basis as the audited consolidated financial statements and have included all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of our financial position and operating results for such period. Our historical results are not necessarily indicative of the results that may be expected or may actually occur in the future, and our interim results are not necessarily indicative of the expected results for future interim periods or the full year. The selected financial data should be read together with our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

The following table is presented in thousands, except for share and per share data:

	Year Ended December 31,		Six Months Ended June 30,	
	2016	2017	2017	2018
			(unaudited)	
Statements of Comprehensive Loss:				
Net revenue	$ —	$ 128	$ —	$ 12
Cost of goods sold	—	118	—	5
Gross profit	—	10	—	7
Operating expenses				
Research and development	$ 12,510	$ 12,332	$ 5,827	$ 10,721
General and administrative	4,457	4,823	2,417	3,071
Sales and marketing	517	1,029	399	1,359
Total operating expenses	17,484	18,184	8,643	15,151
Loss from operations	(17,484)	(18,174)	(8,643)	(15,144)
Other income (expense), net	83	113	36	(108)
Net loss	$ (17,401)	$ (18,061)	$ (8,607)	$ (15,252)
Foreign currency translation adjustment	—	588	69	(3)
Comprehensive loss	$ (17,401)	$ (17,473)	$ (8,538)	$ (15,255)
Net loss per share, basic and diluted[1]	$ (7.52)	$ (7.04)	$ (3.60)	$ (5.43)
Weighted-average shares used to compute basic and diluted net loss per share[1]	2,313,526	2,564,964	2,389,066	2,811,183
Pro forma net loss per share, basic and diluted[1][2][3] (unaudited)		$ (0.98)		$ (0.82)
Pro forma weighted-average shares used to compute basic and diluted net loss per share[1][2][3] (unaudited)		18,378,261		18,624,480

(1) See Note 1 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per common share and the shares used in the computation of the per share amounts.

(2) The pro forma net loss per share of common stock, basic and diluted, for the year ended December 31, 2017 and the six months ended June 30, 2018 reflects: (i) the automatic exchange of the exchanged preferred stock immediately prior to the completion of this offering, (ii) the automatic conversion of all outstanding shares of our preferred stock, including the exchanged preferred stock, into 15,813,297 shares of our common stock upon completion of this offering, (iii) the automatic conversion of outstanding warrants to purchase shares of our Series C preferred stock into warrants to purchase 40,001 shares of our common stock in connection with the completion of this offering, and the resulting reclassification of such warrants from a current liability to stockholders' equity (deficit), and (iv) the filing and effectiveness of our certificate of incorporation, which will occur immediately prior to the completion of this offering. Does not reflect (i) $10.0 million in additional borrowings we requested under the Loan Agreement in October 2018, which we expect to receive prior to the closing of this offering, and (ii) the related concurrent issuance of warrants to purchase shares of our Series C preferred stock, which will become exercisable for 39,999 shares of our common stock immediately prior to the closing of this offering at an exercise price of $7.50 per share.

(3) The pro forma net loss per share of common stock, basic and diluted, does not give effect to the issuance of shares from the proposed initial public offering nor do they give effect to potential dilutive securities where the impact would be anti-dilutive.

The following table is presented in thousands:

	As of December 31,		As of June 30,
	2016	2017	2018
	(restated)		(unaudited, restated)
Balance Sheets Data:(1)			
Cash, cash equivalents and short-term investments	$ 8,209	$ 24,398	$ 39,881
Property and equipment, net	1,167	1,530	1,459
Intangible asset, net	656	541	483
Total assets	10,856	29,412	45,800
Total liabilities	1,787	2,540	14,024
Convertible preferred stock	45,350	62,226	82,126
Noncontrolling interest in Axonics Europe S.A.S.	13,150	31,066	31,066
Additional paid-in capital	1,843	2,900	3,230
Stock subscription receivable(2)	(1,178)	(1,753)	(1,824)
Accumulated deficit	(49,105)	(67,166)	(82,418)
Total stockholders' deficit	(49,431)	(66,421)	(81,418)

(1) See Note 10 to our consolidated financial statements appearing elsewhere in this prospectus for more information on the restatements of certain of our financial statements, including our consolidated balance sheets.

(2) Includes outstanding promissory notes as of June 30, 2018, with an aggregate principal balance of $1,782,268.70, that were issued to us by certain of our executive officers and directors in exchange for the exercise of an aggregate of 1,653,196 shares of common stock pursuant to stock option awards. We have entered into debt forgiveness and cancellation of note agreements with certain of our executive officers and directors, including each of our named executive officers, to terminate each of their respective promissory notes and to forgive all respective obligations for payment thereof in connection with this offering. See "Certain Relationships and Related Party Transactions—Loans to Officers and Directors."

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis gives effect to the restatement of our consolidated financial statements as described in Note 10 to our consolidated financial statements included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Forward-Looking Statements and Statistical Data" in this prospectus.

Overview

We are a medical technology company focused on the design, development, and commercialization of innovative and minimally invasive SNM solutions. SNM therapy is primarily used to treat patients with OAB, FI, and UR. Our 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 OAB, FI, and UR. We believe our proprietary r-SNM System offers significant advantages, including being the first and only rechargeable SNM system that is designed to be 60% smaller than existing technology and to last approximately 15 years. We currently have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR, and expect to submit a PMA application to the FDA for UUI, a predominant OAB subtype, during the first quarter of 2019. We believe our r-SNM System has the potential to disrupt and grow the approximately $605 million global SNM market in 2017, which is currently controlled by a single participant.

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

In the United States, the cost required to treat each patient is reimbursed through various third-party payors, such as commercial payors and government agencies. Most large insurers have established coverage policies in place to cover SNM therapy. Certain commercial payors have a patient-by-patient prior authorization process that must be followed before they will provide reimbursement for SNM therapy. Outside the United States, reimbursement levels vary significantly by country and by region, particularly based on whether the country or region at issue maintains a single-payor system. SNM therapy is eligible for reimbursement in Canada, Australia, and certain countries in the EU, such as Germany, France, and the United Kingdom. Annual healthcare budgets generally determine the number of SNM systems that will be paid for by the payor in these single-payor system countries and regions.

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

We have devoted substantially all of our resources to research and development activities related to our r-SNM System, including clinical and regulatory initiatives to obtain marketing approvals. In anticipation of potential FDA approval, we expect to spend a significant amount of our existing resources on sales and marketing activities as we begin to commercialize and market our r-SNM System in the United States. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. We incurred net losses of $17.4 million, $18.1 million, and $15.3 million for the years ended December 31, 2016 and 2017 and the six months ended June 30, 2018, respectively, and had an accumulated deficit of $82.4 million as of June 30, 2018. As of June 30, 2018, we had available cash, cash equivalents and short-term investments of approximately $39.9 million, current liabilities of approximately $5.0 million, and long-term liabilities of approximately $9.0 million.

To date, we have financed our operations primarily through preferred stock financings and amounts borrowed under the Loan Agreement with Silicon Valley Bank. We have invested heavily in product development and continuous improvement to our r-SNM System. We have also made significant investments in clinical studies to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions. We intend to make significant investments to build our sales and marketing organization by increasing the number of United States and global sales representatives to market our product in markets throughout United States, Canada, Europe, and Australia. We also intend to continue to make investments in research and development efforts to develop our next generation r-SNM System and support our potential future regulatory submissions for expanded labeling and for expansion into additional international markets. Because of these and other factors, we expect to continue to incur net losses for the next few years and we expect to require additional funding, which may include future equity and debt financings. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material and adverse effect on our business, financial condition, and results of operations.

AMF License Agreement

On October 1, 2013, we entered into the License Agreement pursuant to which AMF agreed to license to us the AMF IP to develop and commercialize the AMF Licensed Products. Any and all improvements to the AMF IP made by us will be owned by AMF and licensed to us under the License Agreement for purposes of making AMF Licensed Products.

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

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.

In addition, the License Agreement provides AMF with the option, or the AMF Option, to license from us any intellectual property developed and 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.

Pursuant to the License Agreement, we are obligated to pay a 4% royalty of all net revenue derived from the AMF Licensed Products if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case, subject to certain adjustments.

In 2017, we sold several of our r-SNM Systems as part of a one-time evaluation agreement with a hospital in Canada. As a result, we generated net revenue of $128,118 and recorded related royalties of $4,972 during the fiscal year ended December 31, 2017. No revenue was generated and no payments were made during the fiscal year ended December 31, 2016. In addition, beginning in 2018, we are required to pay AMF a minimum annual royalty, or the Minimum Royalty, payable quarterly if the royalty due is in excess of the Minimum Royalty, which will automatically increase each calendar year thereafter, subject to a maximum amount of $200,000 per year. We have accrued $37,500 as of June 30, 2018 toward AMF Minimum Royalties. Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF the greater of (i) the amount of the 4% royalty referred to above, and (ii) the Minimum Royalty for such calendar year beginning with 2018. We have 60 days to pay AMF this amount, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

The License Agreement was amended twice in February 2014, once in connection with our Series A preferred stock financing, in order to, among other things, include the field of the treatment of urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, within the scope of the licenses granted therein, an option under the License Agreement that required us to pay $1.0 million. In consideration for the inclusion of this field with the scope of the licenses granted in License Agreement, we issued AMF 50,000 shares of our Series A preferred stock.

As of June 30, 2018, AMF holds 888,000 shares of our common stock, 125,000 shares of our Series A preferred stock, and 771,161 shares of our Series B-1 preferred stock. John Petrovich, a member of our board of directors, is the President, Chief Executive Officer, Senior Vice President of Business Development, and General Counsel of AMF.

For additional information about the License Agreement, see “Business—AMF License Agreement.”

Components of Our Results of Operations

Net Revenue

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

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

Cost of Goods Sold and Gross Margin

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

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

Research and Development Expenses

The largest component of our total operating expenses has historically been research and development expenses. Research and development expenses consist primarily of employee compensation, including stock-based compensation, product development, including testing and engineering, and clinical studies to develop and support our r-SNM System, including clinical study management and monitoring, payments to clinical investigators, and data management. Other research and development expenses include consulting and advisory fees, travel expenses, and equipment-related expenses and other miscellaneous office and facilities expenses related to research and development programs. Research and development costs are expensed as incurred. We expect research and development expenses to increase in the future as we develop next generation versions of our r-SNM System and continue to expand our clinical studies to potentially add additional indications and expand to new markets. We expect research and development expenses as a percentage of revenue to vary over time depending on the level and timing of initiating new product development efforts and new clinical development activities.

The following table summarizes our research and development expenses by functional area for the years ended December 31, 2017 and 2016:

	Years Ended December 31,	
	2017	2016
	(in thousands)	
Personnel related	$ 6,031	$ 4,536
Contract fabrication and manufacturing	2,159	3,083
Contract R&D and consulting	1,829	2,747
Clinical development	1,562	1,470
Other R&D expenses	751	674
Total R&D expenses	$12,332	$12,510

The following table summarizes our research and development expenses by functional area for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,	
	2018	2017
	(in thousands) (unaudited)	
Personnel related	$ 3,784	$2,871
Clinical development	2,882	659
Contract fabrication and manufacturing	2,393	1,223
Contract R&D and consulting	1,114	735
Other R&D expenses	548	339
Total R&D expenses	$10,721	$5,827

General and Administrative Expenses

General and administrative expenses consist primarily of employee compensation, including stock-based compensation, and spending related to finance, information technology, human resource functions, consulting, legal, and professional service fees. Other general and administrative expenses include office-related expenses, facilities and equipment rentals, and travel expenses. We expect our general and administrative expenses will significantly increase in absolute dollars as we increase our headcount and expand administrative personnel to support our growth and operations as a public company including finance personnel and information technology services. Additionally, we anticipate increased expenses related to audit, legal, and tax-related services associated with maintaining compliance with regulations, exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company. These expenses may further increase when we no longer qualify as an "emerging growth company" under the JOBS Act, which will require us to comply with certain reporting requirements from which we are currently exempt. We expect general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of trade shows, booth exhibition costs, and the related travel for these events. Other sales and marketing expenses include consulting and advisory fees, market access personnel and employee compensation including stock-based compensation. In anticipation of potential FDA approval, we expect sales and marketing expenses to continue to increase in absolute dollars as we expand our commercial infrastructure to both drive and support our expected growth in revenue. In particular, we plan to hire

approximately 60 sales representatives, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval to support the potential commercial launch in the United States, which will significantly increase our sales and marketing expense. However, we expect sales and marketing expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Other Income (Expense), Net

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

Income Tax Expense

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

Results of Operations

Comparison of the Six Months Ended June 30, 2018 and 2017

The following table shows our results of operations for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,		Period to Period Change
	2018	2017	
	(in thousands) (unaudited)		
Net revenue	$ 12	$ —	$ 12
Cost of goods sold	5	—	5
Gross profit	7	—	7
Gross Margin	*56.3%*	—	
Operating Expenses			
Research and development	10,721	5,827	4,894
General and administrative	3,071	2,417	654
Sales and marketing	1,359	399	960
Total operating expenses	15,151	8,643	6,508
Loss from operations	(15,144)	(8,643)	(6,501)
Other Income (Expense)			
Interest income	276	42	234
Other expense	(383)	(5)	(378)
Other income (expense), net	(107)	37	(144)
Loss before income tax expense	(15,251)	(8,606)	(6,645)
Income tax expense	1	1	—
Net loss	$(15,252)	$(8,607)	$ (6,645)
Foreign currency translation adjustment	(3)	69	(72)
Comprehensive loss	$(15,255)	$(8,538)	$ (6,717)

Net Revenue

Net revenue was minimal for the six months ended June 30, 2018 and was derived from the sale of one r-SNM System to a customer in the United Kingdom. We recorded no revenue for the six months ended June 30, 2017.

Cost of Goods Sold and Gross Margin

Due to the sale referenced above, we incurred minimal cost of goods sold for the six months ended June 30, 2018. We recorded no cost of goods sold for the six months ended June 30, 2017. Gross margin was 56.3% in the six months ended June 30, 2018, compared to no gross margin in the six months ended June 30, 2017.

Research and Development Expenses

Research and development expenses increased $4.9 million, or 84.0%, to $10.7 million in the six months ended June 30, 2018 compared to $5.8 million in the six months ended June 30, 2017. The increase in research and development expenses was primarily attributable to an increase of $2.2 million in clinical development costs to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions, an increase of $1.2 million in contract fabrication and manufacturing costs, an increase of $0.9 million in personnel costs, and an increase of $0.4 million in contract research and development and consulting expenses.

General and Administrative Expenses

General and administrative expenses increased $0.7 million, or 27.0%, to $3.1 million in the six months ended June 30, 2018, compared to $2.4 million in the six months ended June 30, 2017, primarily as a result of an increase of $0.5 million related to personnel costs and an increase of $0.1 million in consulting costs.

Sales and Marketing Expenses

Sales and marketing expenses increased $1.0 million, or 241.1%, to $1.4 million in the six months ended June 30, 2018, compared to $0.4 million in the six months ended June 30, 2017. The increase in sales and marketing expenses was primarily due to an increase of $0.6 million related to personnel costs, an increase of $0.2 million related to expenses for conferences and tradeshows, and an increase of $0.1 million in consulting costs.

Other Income (Expense), Net

Other expense, net was $0.1 million in the six months ended June 30, 2018, consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank, partially offset by interest income earned on cash equivalents and short-term investments. Other income, net was minimal in the six months ended June 30, 2017.

Income Tax Expense

Income tax expense was minimal in the six months ended June 30, 2018 and 2017.

Fiscal Year Ended December 31, 2017 Compared to Fiscal Year Ended December 31, 2016

The following table shows our results of operations for the fiscal year ended December 31, 2017 and 2016:

	Year Ended December 31,		Period to Period Change
	2017	2016	
	(in thousands)		
Net revenue	$ 128	$ —	$ 128
Cost of goods sold	118	—	118
Gross profit	10	—	10
Gross Margin	*7.9%*	—	
Operating Expenses			
Research and development	12,332	12,510	(178)
General and administrative	4,823	4,457	366
Sales and marketing	1,029	517	512
Total operating expenses	18,184	17,484	700
Loss from operations	(18,174)	(17,484)	(690)
Other Income (Expense)			
Interest income	201	84	117
Loss on disposal of property and equipment	(65)	—	(65)
Other expense	(22)	—	(22)
Other income, net	114	84	30
Loss before income tax expense	(18,060)	(17,400)	(660)
Income tax expense	1	1	—
Net loss	$(18,061)	$(17,401)	$ (660)
Foreign currency translation adjustment	588	—	588
Comprehensive loss	$(17,473)	$(17,401)	$ (72)

Net Revenue

To date, we have generated minimal revenue. In fiscal year 2017, we sold several of our r-SNM Systems as part of a one-time evaluation agreement with a hospital in Canada, resulting in net revenue of $0.1 million compared to no revenue in fiscal year 2016. This evaluation agreement represented a one-time professional courtesy supply for the hospital due to product shortfall, of which we supplied at discounted prices. We have no continuing or accruing obligations under the evaluation agreement and therefore have not generated revenue in fiscal year 2018 under such agreement. We did not sell our r-SNM System in any other region in fiscal year 2017.

Cost of Goods Sold and Gross Margin

The sale to a hospital in Canada referenced above resulted in cost of goods sold of $0.1 million in fiscal year 2017 compared to no cost of goods sold in fiscal year 2016. Gross margin was 7.9% in fiscal year 2017 compared to no gross margin in fiscal year 2016.

Research and Development Expenses

Research and development expenses decreased $0.2 million, or 1.4%, to $12.3 million in fiscal year 2017 compared to $12.5 million in fiscal year 2016. The decrease in research and development expenses was primarily attributable to a decrease of $0.9 million in contract fabrication and manufacturing expenses as we

obtained European regulatory approval and began capitalizing inventory in fiscal year 2017, a decrease of $0.9 million in contract research and development and consulting expenses, partially offset by an increase of $1.5 million in personnel costs due primarily to headcount increases, and to a lesser extent, compensation increases.

General and Administrative Expenses

General and administrative expenses increased $0.4 million, or 8.2%, to $4.8 million in fiscal year 2017 compared to $4.5 million in fiscal year 2016, primarily as a result of an increase of $0.2 million related to personnel costs and $0.2 million in travel expenses.

Sales and Marketing Expenses

Sales and marketing expenses increased $0.5 million, or 99.6%, to $1.0 million in fiscal year 2017 compared to $0.5 million in fiscal year 2016. The increase in sales and marketing expenses was primarily due to an increase of $0.4 million related to travel expenses for our U.S. and European sales personnel to attend conferences and tradeshows.

Other Income, Net

Other income, net remained relatively consistent at $0.1 million in fiscal year 2017 compared to fiscal year 2016.

Income Tax Expense

Income tax expense was minimal in fiscal year 2017 and 2016.

Seasonality

We expect that any revenue we may generate could fluctuate from quarter to quarter as a result of timing and seasonality. We anticipate mild seasonality based on national holiday patterns specific to certain nations. These seasonal variations are difficult to predict accurately, may vary amongst different markets, and at times may be entirely unpredictable. In addition to the above factors, in the United States, it is possible that we may experience seasonality based on patients' annual deductibility. In Europe, we may be required to engage in a contract bidding process in order to sell our r-SNM System, which processes are only open at certain periods of time, and we may not be successful in the bidding process. In addition, it is possible that we may experience variations in demand for our product in the first fiscal quarter of each year in Europe, following publication of new coverage status and changes in hospital budgets pertaining to allocation of funds to purchase products such as our r-SNM System.

Liquidity and Capital Resources

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

We incurred net losses of $17.4 million, $18.1 million, and $15.3 million for the years ended December 31, 2016 and 2017 and the six months ended June 30, 2018, respectively, and had an accumulated deficit of $82.4 million as of June 30, 2018. In anticipation of potential FDA approval, we expect to spend a significant amount of our existing resources on sales and marketing activities as we begin to commercialize and market our r-SNM System in the United States. In particular, we plan to hire approximately 60 sales representatives, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval to support the potential commercial launch in the United States, which will significantly increase our sales and marketing expense.

As of June 30, 2018, we had cash, cash equivalents and short-term investments of $39.9 million and an accumulated deficit of $82.4 million. Through June 30, 2018, we raised an aggregate of $114.2 million in gross proceeds from private placements of our preferred stock. As of December 31, 2017, we had cash and cash equivalents of $24.4 million and an accumulated deficit of $67.2 million. Our primary sources of capital to date have been from preferred stock financings and amounts borrowed under the Loan Agreement with Silicon Valley Bank. In February 2018, we received $10.0 million from Tranche A of the Term Loan simultaneously with our entry in the Loan Agreement. As of June 30, 2018, we had $10.0 million in outstanding borrowings under the Term Loan and an ability to borrow an aggregate of $10.0 million in Tranche B and Tranche C. In October 2018, we requested the full $5.0 million from Tranche B and the full $5.0 million from Tranche C, as discussed below under "—Indebtedness." We believe that our existing cash resources will be sufficient to meet our forecasted requirements for operating liquidity, capital expenditure and debt repayments for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, however, we may seek to sell additional equity, increase the availability under the Loan Agreement or enter into an additional loan agreement. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain additional financing when needed to satisfy our liquidity requirements, we may be required to delay the development, commercialization and marketing of our r-SNM System.

Cash Flows

The following table presents a summary of our cash flow for the periods indicated:

	Year Ended December 31,		Six Months Ended June 30,	
	2017	2016	2018	2017
	(in thousands)		(unaudited)	
Net cash provided by (used in)				
Operating activities	$(18,174)	$(17,336)	$(13,972)	$ (8,424)
Investing activities	(1,039)	(292)	(15,451)	(250)
Financing activities	34,814	1,625	29,758	19,923
Effect of exchange rate changes on cash and cash equivalents	588	—	(3)	69
Net increase (decrease) in cash and cash equivalents	$ 16,189	$(16,003)	$ 332	$11,318

Net cash used in operating activities

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

Net cash used in operating activities was $17.3 million in fiscal year 2016 and consisted primarily of a net loss of $17.4 million, a decrease in net operating assets of $0.9 million, partially offset by non-cash charges of $1.0 million. Net operating assets consisted primarily of accounts payable as vendor purchases were paid. Non-cash charges consisted primarily of depreciation and amortization and stock-based compensation.

Net cash used in operating activities was $14.0 million for the six months ended June 30, 2018 and consisted primarily of a net loss of $15.3 million, partially offset by non-cash charges of $0.8 million and an increase in net operating assets of $0.5 million. Net operating assets consisted primarily of inventory to support the planned launch of our commercial operations. Non-cash charges consisted primarily of depreciation and amortization and stock-based compensation.

Net cash used in operating activities was $8.4 million for the six months ended June 30, 2017 and consisted primarily of a net loss of $8.6 million, a decrease in net operating assets of $0.3 million, partially offset by non-cash charges of $0.5 million. Net operating assets consisted primarily of accounts payable due to timing of payments. Non-cash charges consisted primarily of depreciation and amortization and stock-based compensation.

Net cash used in investing activities

Net cash used in investing activities was $1.0 million in fiscal year 2017 and consisted of purchases of property and equipment. Net cash used in investing activities in fiscal year 2016 was $0.3 million and also consisted of purchases of property and equipment. Net cash used in investing activities was $15.5 million for the six months ended June 30, 2018 and consisted of purchases of short-term investments and property and equipment. Net cash used in investing activities was $0.3 million for the six months ended June 30, 2017 and consisted of purchases of property and equipment.

Net cash provided by financing activities

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

Net cash provided by financing activities was $1.6 million in 2016 and consisted of proceeds from the issuance and sale of our Series B-2 preferred stock.

Net cash provided by financing activities was $29.8 million for the six months ended June 30, 2018 and consisted primarily of $20.1 million of proceeds from the issuance of shares of our Series C preferred stock and $10.0 million of proceeds from our Term Loan with Silicon Valley Bank.

Net cash provided by financing activities was $19.9 million for the six months ended June 30, 2017 and consisted primarily of proceeds from the issuance of shares of our Series C preferred stock.

Indebtedness

In February 2018, we entered into the Loan Agreement with Silicon Valley Bank providing for the Term Loan. Pursuant to the Loan Agreement, we may request up to $20.0 million in three tranches of term loans and such drawn obligations mature on June 1, 2021. We requested $10.0 million from Tranche A simultaneously with the entry into the Loan Agreement, which is currently outstanding. We may request Tranche B of an additional $5.0 million after the date commencing on the later of (i) the date that we achieve positive three months results in our ARTISAN-SNM pivotal study, as confirmed to Silicon Valley Bank by a member of our management team and a member of our board of directors, and (ii) July 1, 2018, and ending on December 31, 2018, and Tranche C, for an additional $5.0 million after the date commencing on the later of (i) the date that Silicon Valley Bank receives evidence, in form and substance reasonably satisfactory to Silicon Valley Bank, that we have received

our PMA in the United States for our r-SNM System or gross proceeds from the sale of our equity securities of not less than $20.0 million (which condition was satisfied when we issued and sold 2,233,333 shares of our Series C preferred stock in March 2018 for aggregate gross proceeds of $20,099,997), and (ii) January 1, 2019, and ending on March 31, 2019, subject to certain terms and conditions. If either Tranche B or Tranche C is requested, then the maturity of the Term Loan is automatically extended to December 1, 2021.

The Loan Agreement provides for monthly interest payments through December 31, 2018; provided that, (i) if we request and Silicon Valley Bank funds Tranche B or Tranche C, this interest-only period automatically extends through June 30, 2019, and (ii) we have received a PMA in the United States for our r-SNM System and we request and Silicon Valley Bank funds Tranche C, the interest-only period automatically extends through December 31, 2019. On the first day of the end of the interest only period, 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%.

In October 2018, we and Silicon Valley Bank entered into an amendment to the Loan Agreement, or the Loan Amendment, in connection with which we requested the full $5.0 million from Tranche B and the full $5.0 million from Tranche C. We expect to receive the $10.0 million from both tranches prior to the completion of this offering. Pursuant to the Loan Amendment, Silicon Valley Bank has agreed to (i) extend the interest only period from June 30, 2019 to December 31, 2019, without requiring our receipt of a PMA in the United States for our r-SNM System, and (ii) make Tranche C available now instead of January 1, 2019. In addition, pursuant to the Loan Amendment, we are obligated to pay Silicon Valley Bank a fee of $100,000 in the event that we do not (i) consummate this offering, with proceeds of no less than $75.0 million , (ii) receive PMA approval in the United States for our r-SNM System, or (iii) receive gross proceeds of at least $40.0 million from the sale of our equity securities, in each case on or prior to June 30, 2019. In addition, as a result of our request of the full $5.0 million from Tranche B and the full $5.0 million from Tranche C, the maturity of the Term Loan has been automatically extended to December 1, 2021.

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), shall also be 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 drawn under the Term Loan.

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

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

- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of our capital stock;

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

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

In addition, we issued warrants to Silicon Valley Bank and Life Science Loans II, LLC, its counterparty. Each warrant entitles the holder thereof to purchase up to 33,333 shares of our Series C preferred stock at an exercise price of $9.00 per share. Initially, each warrant is exercisable for 16,667 shares of our Series C preferred stock. Upon drawing the full $5.0 million from Tranche B, an additional 8,333 shares will be exercisable under each warrant and upon drawing the full $5.0 million from Tranche C, an additional 8,333 shares will be exercisable under each warrant. Each warrant will expire on February 6, 2028. In connection with the completion of this offering, each warrant will convert into warrants to purchase shares of our common stock in accordance with its terms.

We have no further indebtedness arrangements.

Off-Balance Sheet Arrangements

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

Related Party Transactions

Information concerning related party transactions is set forth in the section captioned “Certain Relationships and Related Party Transactions.”

Contractual Obligations

Our principal contractual obligations consist of the operating lease for our headquarters and certain purchase obligations and other liabilities. The following table sets out, as of December 31, 2017, our contractual obligations due by period (in thousands):

		Payments due by period			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations(1)	$ 396	$ 213	$ 183	$ —	$ —
Purchase Obligations(2)	3,418	3,418	—		
Other Long-Term Liabilities(3)	2,825	75	225	325	2,200
Total	$6,639	$ 3,706	$ 408	$ 325	$ 2,200

In February 2018, we entered into the Loan Agreement. The amounts below reflect the obligations under the Loan Agreement, including interest and principal payments and the final payment payable under the Loan Agreement.

The following table sets out, as of June 30, 2018, our contractual obligations due by period (in thousands):

		Payments due by period			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations(1)	$ 290	$ 217	$ 73	$ —	$ —
Purchase Obligations(2)	3,475	3,475	—	—	
Other Long-Term Liabilities(3)	2,788	88	250	350	2,100
Long-term Debt(4)	12,000	2,535	9,465	—	—
Total	$18,553	$ 6,315	$ 9,788	$ 350	$ 2,100

(1) Our principal office is currently located at 26 Technology Drive, Irvine, California 92618, where we lease approximately 25,548 square feet of office space under a lease that terminates on August 13, 2025, or the new lease. In addition, we maintain offices at 7575 Irvine Center Drive, Suite 200, Irvine, California 92618, where we lease approximately 12,215 square feet of space, and where we intend to conduct the training of our sales team, under a lease that terminates on October 31, 2019, or the 7575 Irvine Center lease. As of December 31, 2017 and June 30, 2018, only the 7575 Irvine Center lease was effective. In July 2018, the lease agreement for the new lease was amended to remove the contingency on the termination of the 7575 Irvine Center lease, and the new lease inception date will be the date of occupancy, or in August 2018. The aggregate base rent due over the initial term under the terms of the new lease is approximately $5.3 million (without giving effect to certain rent abatement terms). We will also be responsible for the payment of additional rent to cover certain costs, taxes, and insurance. Based on the estimated monthly additional rent for 2018 as set forth in the new lease, we estimate that the additional rent during the initial term will be approximately $3.8 million. We also expect to pay approximately $0.5 million for leasehold improvements, net of the tenant improvement allowance provided in the new lease of approximately $0.8 million.

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

(3) Represents the Minimum Royalty due under the License Agreement beginning in 2018.

(4) Includes interest payments and the minimum final payment, consisting of a 7.5% premium principal amount paid off under the Loan Agreement, assuming maturity at June 30, 2021 and assuming the principal balance

remains the same. Does not give effect to $10.0 million of additional borrowings under the Loan Agreement in October 2018 or the extended maturity date of December 1, 2021 pursuant to the Loan Amendment.

The tables above do not include our lease obligations under the new lease. Payments under the new lease were contingent on the termination of the 7575 Irvine Center lease until that lease was amended in July 2018. The 7575 Irvine Center lease did not terminate as of December 31, 2017, and as a result, we had no lease obligations under the new lease as of June 30, 2018. The new lease inception date is deemed to be the date of the lease amendment, or July 11, 2018, and lease commencement is August 13, 2018. For the new lease, as of September 30, 2018, (i) our total operating lease obligations are $5,188, (ii) our payments due in the less than one year are $664, (iii) our payments due in one to three years are $1,421, (iv) our payments due in three to five years are $1,554, and (v) our payments due in more than five years are $1,549, in each case, presented in thousands.

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

Critical Accounting Policies and Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires our management to make estimates and judgments that affect the amounts reported in our consolidated financial statements and accompanying notes included elsewhere in this prospectus. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable and supportable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and such differences may be material to our consolidated financial statements.

While our significant accounting policies are more fully described in note 1 to our consolidated financial statements included elsewhere in this prospectus, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue Recognition

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

Revenue recognized during the year ended December 31, 2017 relates entirely to the sale of our r-SNM System to one customer in Canada. We recognized revenue in 2017 when title and risk of loss pass to customers, which is typically when the customer takes possession of the product, when persuasive evidence of an arrangement exists there are no further obligations yet to be performed, pricing is fixed or determinable, and collection is reasonably assured. Effective January 1, 2018, we adopted the provisions of Accounting Standards Codification 606, Revenue from Contracts with Customers. We recognize revenue in 2018 when promised goods

or services are transferred to customers in an amount that reflects the consideration which an entity expects to receive in exchange for those goods or services. Revenue recognized during the six months ended June 30, 2018, relates entirely to the sale of our r-SNM System to a customer in the United Kingdom.

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

Inventory

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

We capitalize inventory produced for commercial sale. Costs associated with developmental products that do not satisfy our inventory capitalization criteria are charged to research and development expense as incurred.

Products that have been approved by certain regulatory authorities are also used in clinical programs to assess the safety and effectiveness of the products for usage that have not been approved by the FDA or other regulatory authorities. The form of product utilized for both commercial and clinical programs is identical and, as a result, the inventory has an “alternative future use” as defined in authoritative guidance. Component materials and purchased products associated with clinical development programs are included in inventory and charged to research and development expense when the product enters the research and development process and no longer can be used for commercial purposes and, therefore, does not have an “alternative future use.”

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

We analyze inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its net realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to our inventory values. We also apply judgment related to the results of quality tests that are performed throughout the production process, as well as the understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre- and post-production processes, and we continually gather information regarding product quality for periods after the manufacturing date. Our r-SNM System currently has a maximum estimated shelf life range of 12 to 27 months and, based on sales forecasts, we expect to realize the carrying value of the product inventory. In the future, reduced demand, quality issues, or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of goods sold.

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

Our r-SNM System inventory manufactured prior to regulatory approval by European and Canadian regulatory bodies consisted of component materials and work-in-process inventory, which was expensed as research and development costs as incurred and was combined with other research and development expenses. While management tracked the quantities of individual product lots, it did not track pre-regulatory approval manufacturing costs and, therefore, the manufacturing cost of our r-SNM System component materials and work-in-process inventory produced prior to regulatory approval is not reasonably determinable. However, based on management's expectations for future manufacturing costs to produce our r-SNM System inventory, management estimates that approximately $0.5 million of commercial r-SNM System inventory was expensed prior to regulatory approval.

We began capitalizing our r-SNM System manufacturing costs as inventory following both the receipt of regulatory approval from the European and Canadian regulatory bodies and our decision to begin to commercialize, which occurred in fiscal year 2017. As of June 30, 2018, we had $0.6 million and $1.3 million of finished goods inventory and component materials inventory, respectively, on hand. As of June 30, 2018, we had minimal work-in-process inventory on hand.

The aggregate selling price of reduced-cost finished goods inventory on hand may be affected by a number of factors including, but not limited to, market demand, future pricing of the product, competition, and reimbursement by government and other payers. At this time, our management cannot reasonably estimate the timing and rate of consumption of reduced-cost component materials and work-in-progress inventory, or the timing of sales of finished goods manufactured with this inventory. The time period over which reduced-cost finished goods inventory is consumed will depend on a number of factors, including the amount of future r-SNM System sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date.

Intangible Asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement. The additional field-of-use was provided in exchange for 50,000 shares of our Series A preferred stock, the fair value of which was $1.0 million at the time of the exchange. The intangible asset was recorded at its fair value of $1.0 million at the date contributed. Amortization of this asset is recorded over the shorter of the patent or legal life on a straight-line basis. The weighted-average amortization period is 8.71 years. We will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date.

Impairment of Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net cash flows that the assets are expected to generate. If said assets are considered to be impaired, the impairment that would be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets to date.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include salary and personnel-related costs, costs of clinical studies and testing, supplies and materials, and outside consultant costs. Costs of clinical studies and testing include fees paid to hospitals and physicians for the enrollment and treatment of patients, related product manufacturing expenses for the products used in the studies, fees paid to contract research organizations, or CROs, other consultants, and other outside expenses.

Our research and development team focuses on our r-SNM System, including our clinical studies, as well as evaluations of improvements and enhancements to our r-SNM System. For the years ended December 31, 2016 and 2017 and six months ended June 30, 2018, we incurred research and development expenses of $12.5 million, $12.3 million and $10.7 million, respectively.

Income Taxes

We account for income taxes using the asset and liability method to compute the difference between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. We have deferred tax assets. The realization of these deferred tax assets may be dependent upon our ability to generate sufficient taxable income in future years. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. We evaluate the recoverability of the deferred tax assets annually.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. We have determined that it has no uncertain tax positions.

Stock-Based Compensation

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

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

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

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

Valuation of Common Stock

Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate

of the fair value of our common stock, including: our financial and operating history; recent equity financings and the related valuations; the estimated present value of our future cash flows; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; the rights, preferences and privileges of our preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies; the lack of marketability of our common stock; and macroeconomic conditions. In addition, our board of directors also considered valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Estimates of fair value are sensitive to such factors.

For valuations after the completion of this offering, our board of directors will determine the fair value of each share of common stock based on the closing price of our common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.

Leases

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

Operating lease ROU asset and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The lease terms may include options to extend or terminate the lease when we are reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Internal Controls and Procedures

In connection with the audits of our consolidated financial statements for the years ended December 31, 2017 and 2016, we concluded that there were material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to accounting and reporting for complex financial instruments and consolidation matters, which resulted in the restatement of our consolidated financial statements for the years ended December 31, 2016 and 2017 and for the six-months ended June 30, 2018 as further described in Note 10 to our consolidated financial statements included elsewhere in this prospectus. A lack of adequate staffing levels resulted in insufficient time spent on review and approval of certain information used to prepare our consolidated financial statements and the maintenance of effective controls to adequately monitor and review significant transactions for financial statement completeness and accuracy. These control deficiencies, although varying in severity, contributed to the material weaknesses in the control environment. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected.

We are taking steps to remediate the material weakness in our internal control over financial reporting, including the implementation of new accounting processes and control procedures and the identification of gaps in our skills base and expertise of the staff required to meet the financial reporting requirements of a public company. We plan to hire additional accounting personnel who are certified public accountants, which will enable us better address the accounting for complex financial instruments or consolidation matters or other complex accounting matters that may occur in the future.

We will be required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the year following our first annual report required to be filed with the SEC. This assessment will need to include disclosure of any material weaknesses identified by management over our internal control over financial reporting. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" if we take advantage of the exemptions contained in the JOBS Act.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are designed and operating effectively, which could result in a loss of investor confidence in the accuracy and completeness of our financial reports. This could cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. See "Risk Factors—Risks Related to this Offering and Our Common Stock—We have identified material weaknesses in our internal control over financial reporting which resulted in the restatement of our consolidated financial statements. If we do not remediate the material weaknesses in our internal control over financial reporting, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our common stock."

Recent Accounting Pronouncements

In May 2014, the FASB issued a comprehensive new revenue recognition standard which will supersede previous existing revenue recognition guidance. The standard is intended to clarify the principles of recognizing revenue and create common revenue recognition guidance between GAAP and International Financial Reporting Standards. The standard also requires expanded disclosures surrounding revenue recognition. During fiscal year 2016, the FASB issued additional clarification guidance on the new revenue recognition standard which also included certain scope improvements and practical expedients. We early adopted this guidance effective January 1, 2018 using the modified retrospective method. The adoption of this guidance did not have a material impact on our consolidated financial statements or related disclosures.

In February 2016, the FASB issued a comprehensive new lease standard which will supersede previous lease guidance. The standard requires a lessee to recognize assets and liabilities related to long-term leases that were classified as operating leases under previous guidance in its balance sheet. An asset would be recognized related to the right to use the underlying asset and a liability would be recognized related to the obligation to make lease payments over the term of the lease. The standard also requires expanded disclosures surrounding leases. We adopted this guidance effective January 1, 2018. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases. Adoption of the standard required us to restate certain previously reported results, including the recognition of additional ROU assets and lease liabilities for operating leases. We recorded an ROU asset of approximately $0.2 million, $0.1 million, and $0.1 million on our consolidated balance sheets at December 31, 2016, December 31, 2017, and June 30, 2018, respectively. We also recorded a lease liability of approximately $0.5 million, $0.3 million, and $0.2 million on our consolidated balance sheets at December 31, 2016, December 31, 2017, and June 30, 2018, respectively. The standard did not have an impact on our consolidated income statements.

In March 2016, the FASB issued authoritative guidance to simplify the accounting for certain aspects of share-based compensation. This guidance addresses the accounting for income tax effects at award settlement, the use of an expected forfeiture rate to estimate award cancellations prior to the vesting date and the presentation of excess tax benefits and shares surrendered for tax withholdings on the statement of cash flows. We adopted

this guidance effective January 1, 2018. This guidance requires all income tax effects of awards (resulting from an increase or decrease in the fair value of an award from grant date to the vesting date) to be recognized in the income statement when the awards vest or are settled which is a change from previous guidance that required such activity to be recorded in paid-in capital within stockholders' equity. Under this guidance, excess tax benefits are also excluded from the assumed proceeds available to repurchase shares in the computation of diluted earnings (loss) per share. This guidance also eliminates the requirement to estimate forfeitures, but rather provides for an election that would allow entities to account for forfeitures as they occur. We made an entity-wide accounting policy election to continue to estimate the number of awards that are expected to vest. The adoption of this guidance did not have a material impact on our consolidated financial statements or related disclosures.

In October 2016, the FASB issued authoritative guidance which amends the accounting for income taxes on intra-entity transfers of assets other than inventory. This guidance requires that entities recognize the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The income tax consequences on intra-entity transfers of inventory will continue to be deferred until the inventory has been sold to a third party. This guidance is effective for fiscal years beginning after December 15, 2017, which was our first quarter of fiscal year 2018, and requires a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. Early adoption is permitted at the beginning of a fiscal year. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements or related disclosures.

In May 2017, the FASB issued authoritative guidance that provides clarification on accounting for modifications in share-based payment awards. This guidance is effective for fiscal years beginning after December 15, 2017, which was our first quarter of fiscal year 2018, with early adoption permitted. The adoption of this guidance is not expected to have an impact on our consolidated financial statements or related disclosures unless there are modifications to our share-based payment awards.

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

JOBS Act

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

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

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

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

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

Quantitative and Qualitative Disclosures About Market Risk

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

Interest Rate Risk

We had cash, cash equivalents and short-term investments of $39.9 million as of June 30, 2018, which came from private placements of our preferred stock and debt financing arrangements. The goals of our investment policy are liquidity and capital preservation and we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash, cash equivalents and short-term investments. Additionally, the interest rate for borrowings under the Loan Agreement is variable. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Foreign Currency Exchange Rate Risk

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

Inflation Risk

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

BUSINESS

Overview

We are a medical technology company focused on the design, development, and commercialization of innovative and minimally invasive sacral neuromodulation, or SNM, solutions. SNM therapy is primarily used to treat patients with overactive bladder, or OAB, fecal incontinence, or FI, and urinary retention, or UR. Our proprietary rechargeable SNM system, or our 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 OAB, FI, and UR. We believe our proprietary r-SNM System offers significant advantages, including being the first and only rechargeable SNM system that is designed to be 60% smaller than existing technology and to last approximately 15 years. We currently have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR, and expect to submit a pre-market approval, or PMA, application to the U.S. Food and Drug Administration, or FDA, for urinary urgency incontinence, or UUI, a predominant OAB subtype, during the first quarter of 2019. We believe our r-SNM System has the potential to disrupt and grow the approximately $605 million global SNM market in 2017, which is currently controlled by a single participant.

We are continuing to develop a growing body of compelling clinical evidence that demonstrates the safety, effectiveness, and sustained benefits of our r-SNM System. We have two clinical studies relating to our r-SNM System, a European study, RELAX-OAB, and a U.S. pivotal study, ARTISAN-SNM. In our clinical work to date, we have implanted 180 patients, with an additional 41 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. These patients are being evaluated at 14 centers in the United States and five in Europe. Out of 129 patients, 119 were directly implanted without an external trial period. We have determined the study's primary endpoint to be the percentage of test responders 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. All patients were evaluated as being "test responders" or "test failures" based on their therapy response at the one-month follow-up. "Test responders" were defined as showing at least a 50% reduction in urgency leaks on a three-day bladder diary at the one-month follow-up. 113 of the 129 patients, or approximately 88%, were determined to be test responders at the one-month follow-up. We have obtained partial three-month data for this study for 110 patients and 95 test responders. The remaining 16 of 129 patients, or approximately 12%, were determined to be test failures at the one-month follow-up. In these partial three-month results, therapy response rate was 96% for test responders and 87% for all patients, and 95% of test responders and 89% of all patients were "very" or "moderately" satisfied with the therapy. We expect that six-month results will be available in the first quarter of 2019. Further, we expect to submit our PMA application to the FDA during the first quarter of 2019. Typically, the PMA review process can take from six to 18 months, with the duration depending on a variety of factors. We plan to continue to collect long-term data out to two years, with the 12-month results anticipated to be available in the third quarter of 2019.

As part of the investigational device exemption, or IDE, approval process for our ARTISAN-SNM pivotal study, the FDA recommended that we should make several modifications to the study design in order for the study to serve as the primary clinical support for a future marketing approval. Although we have not modified the ARTISAN-SNM pivotal study design to address all that the FDA has reiterated, based on the preliminary study results to date, and assuming sufficiently strong results at six months and beyond, we believe we will be able to provide the FDA with reasonable assurance of the safety and effectiveness of our r-SNM System to support its marketing approval.

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 urinary urgency frequency, or UUF. The three-month results were published in the peer-reviewed *Journal of Neurourology and Urodynamics* in February 2018 and 12-month results have been submitted for publication. All patients were directly implanted and evaluated to determine if they were test responders, which was defined as showing at least a 50% reduction in the number of

average leaks or voids per day or a reduction to less than eight voids per day, in each case on a three-day bladder diary, within one month. At three months, results for 48 patients who continued with study follow-up showed a therapeutic response rate of 91% for test responders and 71% for all implanted patients. The therapeutic response rate was sustained at 12 months for the 43 patients who continued with study follow-up, at 94% for test responders and 72% for all implanted patients. During the study, patients experienced clinically meaningful improvements in quality of life, and at 12 months, 84% of test responders and 77% of all patients were “very” or “moderately” satisfied with the therapy provided by our r-SNM System. We are following patients out to two years in this study and may follow patients out to five years at selected study sites.

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 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, an estimated 87 million adults suffer from OAB. The primary OAB subtypes are UUI and UUF. 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, a measure we believe to be generally accepted among the relevant physician community. FI is the inability to control bowel function that could lead to involuntary leakage from the rectum. In the United States and Europe, an estimated 40 million adults suffer from FI. Symptoms of OAB and FI 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 OAB and FI, 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 the approximately three million OAB patients who suffer from UUI and UUF in the United States and Europe. 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, a measure we believe to be generally accepted among the relevant physician community. We believe that approximately two-thirds of patients in the United States with OAB and FI that are treated with SNM therapy have either UUI alone or in combination with another subtype of OAB, or FI. 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.

We also believe that SNM therapy is an effective treatment alternative for the approximately one million patients who suffer from FI in the United States and Europe. We believe that a significant portion of people with FI also suffer from OAB.

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, and medication and other non-implantable treatments are better known to physicians and hospitals than SNM therapy. 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 Neurourology and Urodynamics, by 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 innovative and proprietary r-SNM System offers similar therapeutic benefits and competitive advantages to the only currently available SNM technology, InterStim II System, or InterStim II, offered by Medtronic plc, or Medtronic. We believe that our r-SNM System is the first and only system for SNM therapy with a rechargeable implantable pulse generator, or IPG, 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 on average every 4.4 years, as is the case for patients implanted with InterStim II, which we believe will significantly improve patient experience and reduce the risks of surgery and associated infections. In addition, we believe patients who have historically resisted SNM therapy because of the required multiple surgeries may be more inclined to be treated by our r-SNM System. Further, by reducing the number of replacement surgeries, physicians and facilities can utilize their resources more efficiently. Finally, our technology has the potential to significantly reduce overall costs to the healthcare system. In 2016, we commissioned a study that concluded that a rechargeable SNM system with a 15-year battery life could potentially reduce overall U.S. healthcare costs by up to $12 billion over a 15-year horizon.

We have designed and developed a proprietary method protected by patents, know-how, and trade secrets that enables us to combine ceramic and titanium for the IPG enclosure of our r-SNM System. This method enables us to incorporate a significantly smaller recharging coil into our IPG, which offers benefits such as 60% smaller size and half the weight of InterStim II and enhanced communication range. In addition, we also engineered our IPG to deliver constant current stimulation, which adapts to the body's physiological changes, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. Further, our r-SNM System offers significant wireless charging benefits and an easy-to-use patient remote control. Finally, we designed and custom built a touchscreen clinician programmer that guides the implanting physician through electrode placement and stimulation programming. We also intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System. Our goals include introducing market differentiating 1.5T/3.0T magnetic resonance imaging, or MRI, full body conditional labelling for our r-SNM System, reducing by half the number of IPG battery recharging sessions required for the IPG to remain charged for one full month, introducing features that would enable us to connect our IPG to an already implanted InterStim II lead, and expanding the suite of product solutions available for SNM therapy over time.

Our r-SNM System consists of several components and accessories that provide a smoothly integrated, long-lasting, intuitive, and easy-to-use system. The miniaturized IPG 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 IPG and, if a temporary lead was used for the external trial period, implantation of the permanent lead. The IPG 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 IPG pocket and connected to the IPG. The IPG 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 IPG is wirelessly charged with an interval of approximately one hour once every two weeks under normal use conditions.

The market for SNM therapy is large and growing. We estimate that the current global SNM market was approximately $605 million in 2017, which represents approximately 41,000 patient implants, including 11,000 patients undergoing replacement implants. We believe that nearly 90% of sales in this market are generated in the United States. We believe our market consists of approximately four million adults in the United States and Europe who suffer from symptoms of either OAB or FI and who are readily treatable with, and eligible candidates for, SNM therapy, with approximately half of that market represented by the United States. Further, we estimate that the global annual addressable SNM market is presently approximately one percent penetrated.

We believe this represents a compelling opportunity for our r-SNM System to capture market share and further penetrate and grow the current U.S. market.

We intend to focus the significant majority of our sales and marketing efforts in the United States where reimbursement for SNM therapy is well established and covered by most major U.S. insurers. We plan to build a specialized and dedicated direct sales organization, which will initially target the estimated 850 physician specialists that represent a majority of the implant volume in the United States. We estimate that approximately 75% of U.S. implant volume is generated by less than 1,000 physicians. In addition, we plan to strategically expand into international markets. We will initially endeavor to hire a specialty sales force of approximately 60 sales representatives in anticipation of our potentially receiving FDA approval to support the commercial launch of our r-SNM System in the United States. Further, we expect to grow our sales force over time and the number of our sales representatives at commercial launch will vary and may be higher depending on the duration of the PMA review process.

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 agreed to license to us certain patents and know-how, which we refer to collectively as 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, altogether which we refer to as, 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, InterStim I System, was introduced in 1997, over 300,000 patients have been implanted worldwide with such system and its successor InterStim II. In 2017, we believe that approximately 41,000 patients were implanted with SNM therapy, including 11,000 patients undergoing replacement implants, corresponding to an approximately $605 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 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 IPG 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 on average every 4.4 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. 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 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 for the IPG enclosure enables us to incorporate a significantly smaller recharging coil into our IPG, 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 adapts to the body's physiological changes, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. Further, our r-SNM System is differentiated by significant wireless charging benefits and an easy-to-use patient remote control. Finally, we designed and custom built a touchscreen clinician programmer that guides the implanting physician through electrode placement and stimulation programming. Our clinician programmer allows physicians to connect to a patient's IPG, while the patient is in the physician's care, to access key therapy data that is stored and maintained on the IPG.

- ***Strong clinical data***. We are continuing to develop 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 these partial three-month results, therapy response rate was 96% for test responders and 87% for all patients. We expect that six- and 12-month results will be available in the first quarter of 2019 and the third quarter of 2019, respectively. Our European study, RELAX-OAB, evaluated 51 patients that suffered from UUF and UUI. At three months, results for 48 patients who continued with study follow-up showed a therapeutic response rate of 91% for test responders and 71% for all implanted patients. The therapeutic response rate was sustained at 12 months for the 43 patients who continued with study follow-up, at 94% for test responders and 72% for all implanted patients. We intend to follow patients for at least out to 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.

- ***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 marketing approval in Europe, Canada, and Australia for OAB, FI, and UR, and completed the enrollment and implantation of patients in our ARTISAN-SNM pivotal study. 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 30, 2018, we owned 17 issued U.S. patents and 20 issued foreign patents, and 17 pending U.S. patent applications and 59 pending foreign patent applications, and we licensed from AMF 30 issued U.S. patents and 38 issued foreign patents, and four pending U.S. patent applications and 28 pending foreign patent applications.

- ***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***. In December 2017, we began enrollment of our ARTISAN-SNM pivotal study. As of June 30, 2018, we had implanted 129 patients and completed the enrollment phase of our study. We anticipate filing our PMA application using six-month results for UUI with the FDA during the first quarter of 2019. Typically, the PMA review process can take from six to 18 months, with the duration depending on a variety of factors.

- ***Continue to promote awareness of our r-SNM System among healthcare providers***. We believe that of the approximately 47,000 specialist 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 850 physician specialists who represent a majority of the implant volume in the United States. We intend to help physicians in their direct-to-patient outreach if and when our r-SNM System is approved by the FDA, 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.

- ***Build a commercialization infrastructure with a specialized direct sales and marketing team***. We plan to establish a commercial infrastructure in anticipation of potential FDA approval of our r-SNM System. 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. Our goal is to hire a specialty sales force of approximately 60 sales representatives, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval to support the commercial launch of our r-SNM System in the United States and we expect to grow our sales force over time and the number of our sales representatives at commercial launch will vary and may be higher depending on the duration of the PMA review process. While our commercial focus is in the United States, we also plan to strategically expand 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 market differentiating 1.5T/3.0T magnetic resonance imaging, or MRI, full body conditional labelling for our r-SNM System, reducing by half the number of IPG battery recharging sessions required for the IPG to remain charged for one full month, introducing compatibility features that would enable us to connect our IPG to an already implanted InterStim II lead, and expanding the suite of product solutions available for SNM therapy over time. Additionally, we intend to pursue regulatory approval for other indications in the United States in the future.

- ***Further penetrate the addressable 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 IPG 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

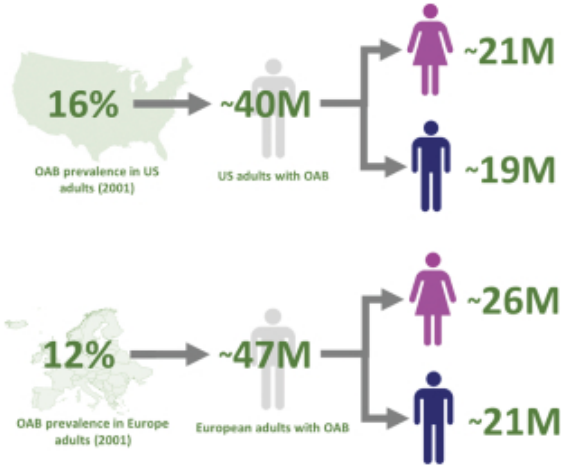
We believe our addressable market consists of approximately four million adults in the United States and Europe who suffer from symptoms of either OAB or FI and who are readily treatable with, and eligible candidates for, SNM therapy. Specifically, we believe this four million adult market consists of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

The market for SNM therapy is large and growing. We believe that the global SNM market was approximately $605 million in 2017, 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 41,000 patient implants, including 11,000 patients undergoing replacement implants, with nearly 90% of sales in this market being generated in the United States and approximately 85% of sales revenue coming from new implant volume. Further, we estimate that the global annual addressable SNM market is presently approximately one percent penetrated. We estimate the global annual SNM market will continue to increase for the foreseeable future driven by increased awareness and education of SNM as a therapy alternative, greater expectations for quality of life, and improved patient attitudes toward receiving medical attention. In addition, market growth could accelerate due to more than one medical device company being focused on this market, new innovation for SNM therapy, and other potential products being introduced to physicians and patients. We believe that this represents a compelling opportunity for our r-SNM System to capture market share and further penetrate and grow the existing U.S. market. We have regulatory approvals in Europe, Canada, and Australia for OAB, FI, and UR. We initially intend to pursue regulatory approval in the United States for UUI, a predominant OAB subtype, and we intend to seek regulatory approval for other indications in the United States in the future.

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 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

SNM therapy cannot be used to address 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. In the United States, of the approximately 40 million adult patients with symptoms of OAB, we believe that approximately 15.9 million seek medical attention, with UUI patients more frequently consulting with a physician. Similarly, in Europe, of the approximately 47 million adult patients with symptoms of OAB, we believe that approximately 18.7 million seek medical attention. As a result, we believe that the OAB population in the United States and Europe who seek medical attention for OAB, which we refer to as the managed population in the graphic below, is approximately 34.6 million.

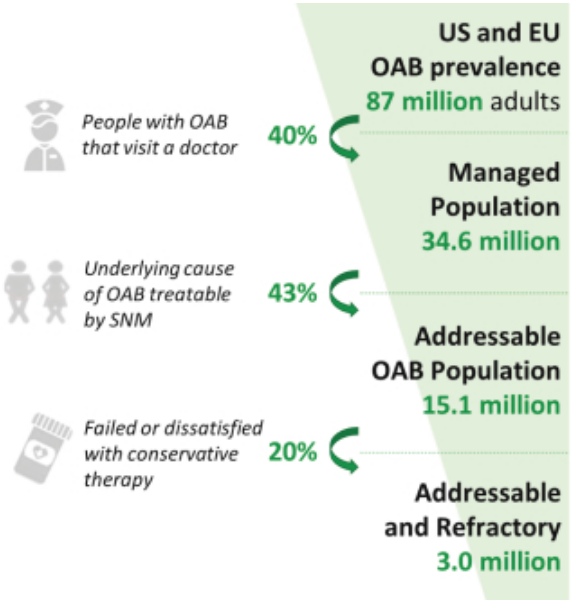
Of the approximately 15.9 million patients who seek medical attention in the United States for the treatment of symptoms of OAB, we believe that approximately 6.8 million are addressable with SNM therapy.

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

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

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

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



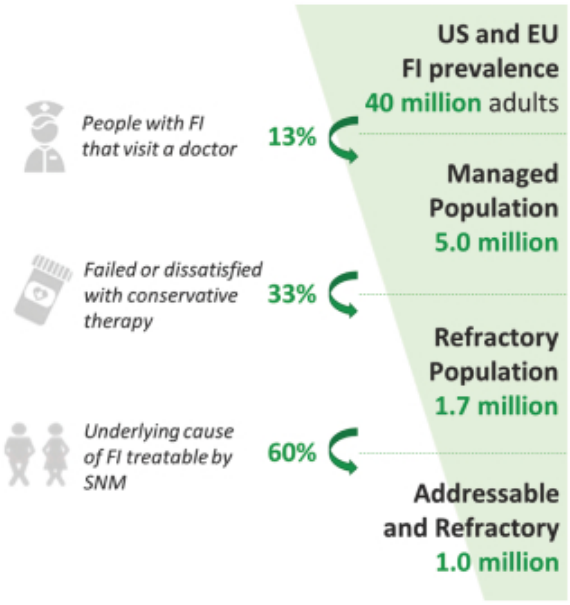
Fecal Incontinence

SNM therapy cannot be used to address 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. In the United States and Europe, based on published results from surveys of patients with FI, of the approximately 40 million adults with symptoms of FI, we believe that approximately five million people seek medical attention, which we refer to as the managed population in the graphic below.

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

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

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



Current Treatments and Limitations

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

- *First-line therapy*: behavioral changes, including conservative treatment options such as diet, exercise, timed voiding, pelvic floor exercises, and biofeedback;

- *Second-line therapy*: drug therapy, including two classes of OAB drugs, anti-muscarinics and beta-3 adrenergic agonists, with patients often trying multiple drugs; and

- *Third-line therapy*: minimally invasive therapy consisting of SNM, BOTOX injections and PTNS.

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

First-Line Therapies

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

Second-Line Therapies

Second-line therapies consist of medications, which comprise the largest segment of the OAB treatment market, estimated at $3.6 billion in 2017. Anticholinergics such as Oxybutynin, Vesicare, Detrol, Oxytrol, Enablex, and Sanctura are the most commonly prescribed medications. However, patients often do not fully comply with their drug prescriptions, due to perceived inefficacy and side effects. Mirabegron is the only available beta-3 adrenergic agonist that targets the bladder muscles and reduces bladder contractions and was approved in 2012 to treat OAB. Physicians may also prescribe Tricyclic antidepressants such as Duloxetine and Imipramine, which are not FDA approved to treat the symptoms of OAB, but have been shown to relax the muscles in the bladder and reduce urgency.

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

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

Third-Line Therapies

Sacral Neuromodulation

Historically, SNM therapy has been the most common form of third-line therapy treatment for OAB. InterStim II, the only currently available SNM system, was approved to treat the symptoms of OAB by the FDA in 2005, and to treat the symptoms of FI by the FDA in 2011, and its predecessor, InterStim, was approved to treat the symptoms of OAB by the FDA in 1997 and 1999 for UUI and UUF, respectively. These systems have been implanted in over 300,000 patients worldwide, with a majority of all implants having taken place in the United States. In 2017, approximately 41,000 patients were implanted with these systems, including 11,000 patients undergoing 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 OAB and FI. We currently have marketing approvals in Europe, Canada, and Australia with indications for UUI, UUF, UR, and FI. We expect to submit our PMA application with the FDA for UUI during the first quarter of 2019, which completed enrollment of 129 patients in June 2018. Typically, the PMA review process can take from six to 18 months, with the duration depending on a variety of factors.

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

Implantable Components for Patient

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

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

External Components for Patient

- Wireless charging device, which allows transcutaneous charging of the IPG. 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.

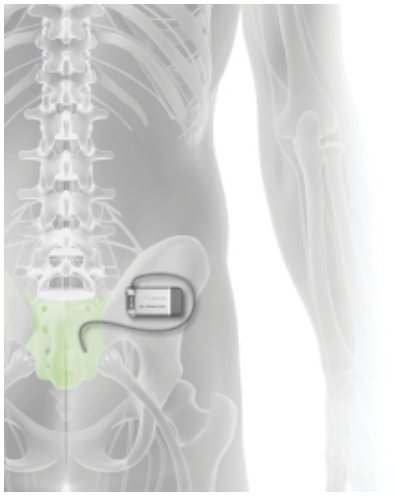
- Wireless remote control that communicates with the device at a range of up to approximately three feet, which is a small and easy-to-use device that allows the patient to adjust stimulation intensity levels and turn on or off stimulation. The remote control includes a light-emitting diode light that indicates therapy intensity and the status of remaining battery life of the IPG.

Implantable Pulse Generator

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 IPG and the four-electrode lead:



Benefits of our r-SNM System

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

- **Safe, effective and durable treatment**. For over 20 years, SNM therapy has been proven to be an effective and durable treatment alternative for patients with OAB and FI. Further, our r-SNM System in our RELAX-OAB study showed compelling safety and effectiveness data, with OAB therapeutic response of 94% for test responders at 12-months.

- **Long-term solution**. We believe that our r-SNM System is the first and only system for SNM therapy with a rechargeable IPG 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 on average every 4.4 years, as is the case for patients implanted with the non-rechargeable InterStim II, which significantly improves patient experience and reduces the risks of surgery and associated infections.

- **Material benefits to physicians and payors**. The reduced number of replacement procedures allows physicians and facilities to utilize their resources more efficiently. Importantly, 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.

- **Smaller and lighter IPG**. Since our r-SNM System's IPG casing combines ceramic and titanium, we have been able to design our IPG to be 60% smaller, and half the weight of InterStim II, which is designed to be more comfortable for patients and reduce pain at the implant site.

- **Constant current**. We have engineered our r-SNM System to have constant current, which is important because it adapts to the body's physiological changes, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. To determine the requisite amount of constant current for SNM therapy, we divide voltage by impedance. Our IPG then adjusts to impedance change and allows a patient to maintain stimulation in what we believe to be an optimum therapeutic range. InterStim II uses voltage control, which results in less electrical pulse current reaching the targeted nerve once the surrounding tissue conductivity decreases, resulting in less reliable stimulation and typically more patient visits for stimulation reprogramming.

- **Improved patient experience**. We designed our r-SNM System based on patient feedback to provide an improved patient experience. Our r-SNM System is differentiated by a wireless charging system with haptic tones and vibrations, and a discrete, small and easy-to-use remote control. Our r-SNM System offers efficient wireless recharging with an interval of approximately one hour once every two weeks under normal use conditions.

- **Simplified physician implantation and programming**. We designed and custom built a touchscreen clinician programmer that guides the implanting physician through electrode placement and stimulation programming. In addition, our clinician programmer allows physicians to connect to a patient's IPG, while the patient is in the physician's care, to access key therapy data that is stored and maintained on the IPG.

Overview of our External Trial System

Our external trial system 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 external trial system is the same remote control used in our permanent r-SNM System. In addition, our external trial system 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 external trial system.

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 IPG, while the patient is in the physician's care, to access key therapy data that is stored and maintained on the IPG.

Clinician Programmer

We designed and custom built our touchscreen clinician programmer. The IPG is programmed by, and wirelessly communicates at a range of up to approximately three feet 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 IPG data and its complete history. The clinician programmer records and stores all data from the IPG 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 such as UUI, UUF, and UR who are not candidates for more conservative therapies. This therapy is not intended for patients with a mechanical obstruction such as benign prostatic hyperplasia, a tumor, or urethral stricture. Further, the therapy is not indicated for pregnant women, or pediatric use.

SNM therapy for bowel control is indicated for the treatment of FI in 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 under an hour, is generally performed in the office or outpatient setting and typically involves a percutaneously placed lead, which a physician implants near the targeted sacral nerve using a needle, with the location confirmed utilizing fluoroscopy and intraoperative muscle responses evoked by test stimulation. The lead is then connected to a

temporary, disposable external trial system which provides stimulation for the therapy. The trial period can last between a few days and several weeks after which the physician evaluates the effectiveness of SNM therapy through several measures, including urinary or fecal episodes and patient satisfaction. Approximately 70% 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 IPG implant procedure. The permanent implant procedure typically occurs in a hospital or outpatient setting, usually lasting under an hour, and includes implantation of the IPG and, if a temporary lead was used for the trial, implantation of the permanent lead. The IPG 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 IPG pocket and connected to the IPG.

Activation and Programming

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

Our Clinical Results and Studies

We are continuing to develop a growing body of compelling clinical evidence that demonstrates the safety, effectiveness, and sustained benefits of our r-SNM System. We have two clinical studies relating to our r-SNM System, a European study, RELAX-OAB, and a U.S. pivotal study, ARTISAN-SNM. We have implanted 51 patients in our RELAX-OAB study and 129 patients in our ARTISAN-SNM pivotal study, and 41 in our investigator-initiated case series and commercially.

Our RELAX-OAB study that began in June 2016 evaluated 51 patients at seven sites in Europe that suffered from OAB subtypes UUI and/or UUF. A subset of the patients suffered from both UUI and UUF. Patients in the study were directly implanted without an external trial period. Within the first month, we evaluated the patients to determine if they were a test responder to the therapy, which we refer to collectively as test responders. Patients were considered test responders if they experienced (i) for patients suffering from UUI, at least a 50% reduction in the average number of leaks per day or (ii) for patients suffering from UUF (a) at least a 50% reduction in the average number of voids per day or (b) a reduction to less than eight voids per day, in each case based on a three-day bladder diary. For the subset of patients who suffered from both UUI and UUF, if a patient qualified as a test responder for either UUI or UUF, that patient was considered a test responder to the therapy. At one month, 71% of patients were test responders to the therapy. At three, six and 12 months, OAB response rate for the test responders was 91%, 94%, and 94%, respectively. 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 three-month results were published in the peer reviewed *Journal of Neurourology and Urodynamics* in February 2018 and the 12-month results have been submitted for publication. We are following patients out to two years in this study and may follow patients out to five years at selected study sites.

In June 2018, we completed the enrollment and implantation of 129 patients with UUI for our ARTISAN-SNM pivotal study. These patients are being evaluated at 14 centers in the United States and five centers in Europe. Out of 129 patients, 119 were directly implanted without an external trial period. We have determined the study’s primary endpoint to be the percentage of test responders 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. All patients were evaluated as being “test responders” or “test failures” based on their

therapy response at the one-month follow-up. “Test responders” were defined as showing at least a 50% reduction in urgency leaks on a three-day bladder diary at the one-month follow-up. 113 of 129 patients, or approximately 88%, were determined to be test responders at the one-month follow-up. The remaining 16 of 129 patients, or approximately 12%, were determined to be test failures at the one-month follow-up. We have obtained partial three-month data for this study for 110 patients and 95 test responders. In these partial three-month results, therapy response rate was 96% for test responders and 87% for all patients, and 95% of test responders and 89% of all patients were “very” or “moderately” satisfied with the therapy. We expect that six-month results will be available in the first quarter of 2019. Further, we expect to submit our PMA application with the FDA during the first quarter of 2019. Typically, the PMA review process can take from six to 18 months, with the duration depending on a variety of factors. 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 FI 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.

RELAX-OAB Study

Overview

We sponsored the RELAX-OAB study, a multicenter, prospective, single-arm, unblinded study conducted as a post-market 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 body mass index, or 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 were published in the peer reviewed *Journal of Neurourology and Urodynamics* in February 2018 and the 12-month results have been submitted for publication. 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

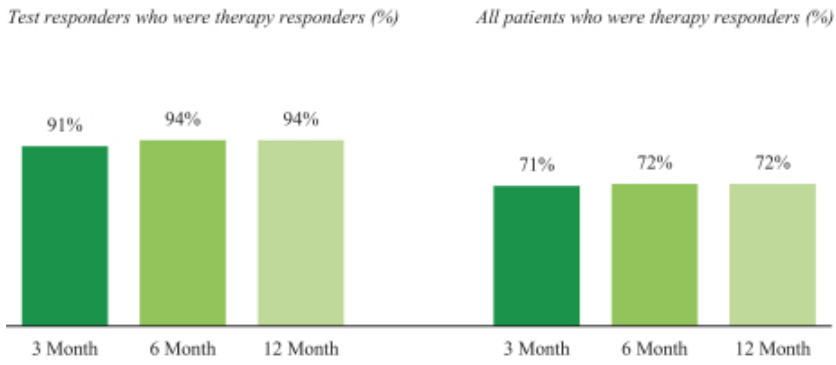
	3 Month	6 Month	12 Month
Number of Patients (#)	**34**	**34**	**32**
Composite Quality of Life Score			
Total Score (#)	+27.3	+25.8	+22.9
Subscales			
Concern	+27.5	+25.3	+24.0
Coping	+33.5	+32.5	+26.6
Sleep	+25.1	+23.5	+19.1
Social Interaction	+19.3	+18.1	+19.0

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

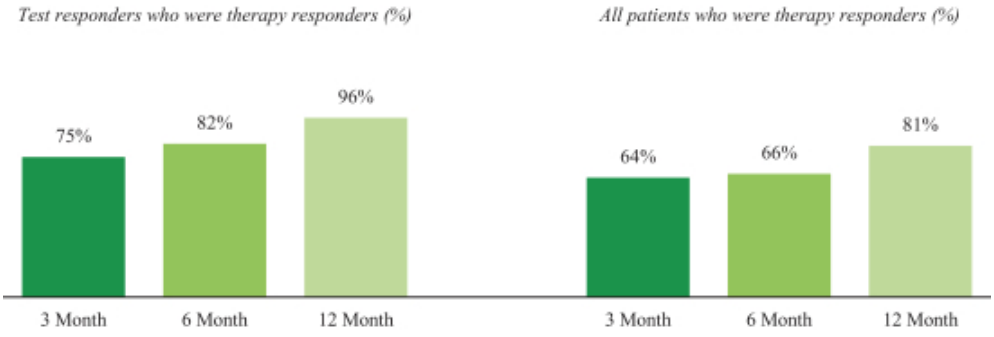


UUI Response

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



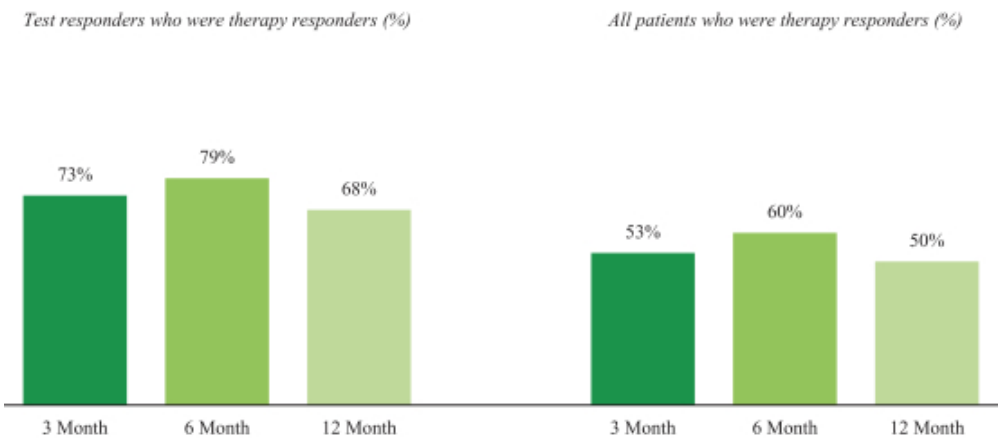
UUF Response

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 leaks and voids per day at three, six, and 12 months, compared to the baseline.

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

ARTISAN-SNM Pivotal Study

Overview

We are sponsoring the ARTISAN-SNM study, a multicenter, single-arm, unblinded prospective study we are conducting under an Investigational Device Exemption, or IDE, from the FDA which was approved in October 2017. 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. We expect to submit our PMA application to the FDA during the first quarter of 2019. Typically, the PMA review process can take from six to 18 months, with the duration depending on a variety of factors.

The study began in December 2017 and is being performed at 14 centers around the United States and five in Europe. As of June 30, 2018, we had implanted 129 patients and completed the enrollment process for this study. Out of 129 patients, 119 were directly implanted without undergoing any external trial period.

All 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, 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 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 “test responders” or “test failures” based on their therapy response at the one-month follow-up visit. “Test responders” were defined as showing at least 50% reduction in urgency leaks on a three-day bladder diary. 113 of the 129 patients, or approximately 88%, were determined to be test responders at the end of the one-month period. The remaining 16 of 129 patients, or approximately 12%, were determined to be test failures at the end of the one-month period.

We have determined the primary effectiveness endpoint for the study to be the percentage of test responders that are therapy responders at six months post implant. We define therapy response as at least a 50% reduction in number of urgency leaks per day on a three-day bladder diary. 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 three, six, 12, 18 and 24 months for test responders and all patients.

As part of the IDE approval process for our ARTISAN-SNM pivotal study, the FDA recommended that we make several modifications to the study design in order for the study to serve as the primary clinical support for a future marketing approval. In response, we have engaged with FDA regarding its recommendations, including our latest IDE supplement, which we submitted to the FDA in September 2018. As a result, we incorporated a number of recommended study modifications. On October 19, 2018, the FDA approved our latest IDE supplement and removed certain of its prior study design recommendations. However, the FDA also continues to reiterate several of its recommended study modifications, including those described below.

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

Specifically, the following FDA recommended modifications to our ARTISAN-SNM pivotal study were not, or are not anticipated to be and at this point certain of these cannot be, incorporated:

- *Exclude patients with MUI, which means a patient has both stress urinary incontinence and UUI.* The FDA noted that post-hoc exclusion of data from patients with significant stress urinary incontinence will not be allowed. Although we did not exclude MUI patients from enrollment, the study design was adjusted to revise the primary endpoint to a reduction of urgency leaks only. Inclusion criteria were designed to ensure that the study population consists of subjects that have at least 50% of leaks associated with urgency and exclusion criteria prohibit inclusion of subjects that were treated surgically for stress urinary incontinence during the period starting six months prior to implant and through the primary endpoint. We do not intend to post-hoc exclude any patients because of MUI.

- *Use either a seven-day bladder diary or two separate three-day bladder diaries.* The ARTISAN-SNM pivotal study utilizes a single three-day bladder diary to evaluate patient urinary symptoms because we believe expert physicians, clinical guidelines, and clinical literature support the validity of the three-day bladder diary and provide evidence of the burden and complication of longer duration diaries.

- *Use a 12-month primary effectiveness endpoint in order to account for the placebo effect and enable assessment of durability of the treatment effect*. We expect to submit our PMA application to the FDA during the first quarter of 2019. We expect to include six-month efficacy data with our PMA application. Prior SNM studies demonstrate the durability of SNM treatment from three months to 12 months, with minimal drop-off in success rates over time. Placebo effect for this type of device is traditionally associated with the external trial period, whereas there was no external trial in the ARTISAN-SNM pivotal study that could be invoked to suggest a placebo effect. We believe gathering six-month efficacy data addresses the concern regarding placebo effect. Further, when the full cohort reaches six-month follow-up, we expect to have nine-month follow-up data for part of the cohort and intend to provide this data to the FDA, as part of the PMA. If the six-month data is not deemed adequate, we expect to have 12-month data for the full cohort in third quarter of 2019, which data we expect to be able to provide to the FDA at such time.

- *Use all patients in whom an implant is attempted, not test responders, for primary efficacy analysis*. We included the “all patients” population in the secondary endpoints and ensured the study size was sufficient to meet the secondary endpoints. We intend to provide the FDA with statistical analysis of the therapy response rate in all subjects. 128 of 129 of the implanted patients are currently active in the study. We have not changed the study design to use a primary endpoint based on “all patients” because we believe our primary endpoint is consistent with other clinical studies in the field.

We believe the implementation of the study design modifications in our September 2018 IDE supplement will not result in a significant delay to the study because the modifications are not regarding the conduct or design of the study, but are instead regarding modifications to the analysis of the study data, which is anticipated to take place in early 2019. Although we have not modified the ARTISAN-SNM study design to address all of the above considerations that the FDA has reiterated, based on the preliminary study results to date, and if we achieve sufficiently strong results at six months and beyond, we believe we will be able to provide the FDA with reasonable assurance of the safety and effectiveness of our r-SNM System to support its marketing approval. Nevertheless, it is possible that the FDA could disagree with our study design and require revisions to the study or data from an additional study before approving our PMA. See “Risk Factors—Risks Related to Our Business and Strategy—We currently depend entirely on the successful and timely regulatory approval from the FDA and commercialization of our r-SNM System, our only product. Our r-SNM System may not receive FDA regulatory approval or we may be significantly delayed in receiving regulatory approval. Even if we receive regulatory approval, we may not be able to successfully commercialize our r-SNM System.”

Partial Three-Month Study Results

As of the date of this prospectus, only partial three-month results are available for 110 out of 129 patients and 95 out of 113 test responders, as presented below.

Therapy Response

Of the 110 implanted patients that have reached the three-month follow-up, 110 completed the three-month follow-up with no major protocol deviations. At the three-month follow-up, 96 of 110 implanted patients, or approximately 87%, were therapy responders, including 91 of 95 test responders, or approximately 96%. 72 of all patients, or approximately 66%, had at least a 75% reduction in urgency leaks and 34 of all patients, or approximately 31%, were completely dry, as illustrated in the table below.

ARTISAN-SNM—Therapy Response Rate

	Test Responders 3 Month	All Patients 3 Month
Number of Patients (#)	95	110
Therapy Responders (# (% of patients))		
UUI Responders	91 (96%)	96 (87%)
UUI Responder Details (# (% of responders))		
50-74% improvement in the number of average urgency leaks per day	22 (24%)	24 (25%)
75-99% improvement in the number of average urgency leaks per day	35 (38%)	38 (40%)
100% improvement in the number of average urgency leaks per day	34 (37%)	34 (35%)

Test responders showed significant improvement in their urgency leaks at three months. Urgency leaks of test responders were reduced from 5.5 (±0.3, standard error) per day at baseline to 1.0 per day (±0.1). 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 1.5 per day (±0.2), as illustrated in the table below.

ARTISAN-SNM—UUI Symptoms

	Test Responders		All Patients	
	Baseline	3 Month	Baseline	3 Month
Number of Patients (#)	113	95	129	110
UUI Symptoms				
Leaks Per Day	5.5	1.0	5.6	1.5

Patient Satisfaction and Recharging Experience

At three months, 95% of test responders were “very” or “moderately” satisfied with the r-SNM therapy and 89% of all patients were “very” or “moderately” satisfied with the r-SNM therapy. Additionally, 95% of test responders and 89% of all patients reported that they would “definitely” or “probably” undergo r-SNM therapy again. The acceptability of charging was “moderately” or “very” acceptable for 95% of test responders and 94% of all patients. 88% of test responders and 87% of all patients reported that it was “moderately” or “very 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 the r-SNM system.

Device-related AEs were reported, which occurred in 8 patients, or 6% of all patients. The most common device-related AE was discomfort due to stimulation, which was reported by 4 patients as 4 separate events. All of these events were successfully resolved with reprogramming the stimulation settings. Pain at the implant site occurred in 2 of 129 patients, or 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 were no reports of lead fracture.

Explants

We explanted the r-SNM System in one patient four weeks after implantation due to incision site infection.

Six- and 12-Month Study Results

We expect the six- and 12-month results of our ARTISAN-SNM study to be available in the first quarter of 2019 and the third quarter of 2019, respectively.

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

Our primary use of proceeds from this offering is to hire a specialty sales force of approximately 60 sales representatives, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval to support the commercial launch of our r-SNM System in the United States. Further, we expect to grow our sales force over time and the number of our sales representatives at commercial launch will vary and may be

higher depending on the duration of the PMA review process. In anticipation of potential FDA approval, we expect to recruit, hire and train a direct sales force, primarily in the United States. We will seek to recruit representatives with strong sales backgrounds and experience in SNM therapy and other rechargeable and non-rechargeable neurostimulation devices, and with relationships with urologists and urogynecologists. We intend to focus the significant majority of our sales and marketing efforts in the United States because reimbursement for SNM therapy is well-established and covered by most major U.S. insurers.

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 initially target the estimated 850 physician specialists that represent a majority of the SNM implant volume. We estimate that approximately 75% of U.S. implant volume is generated by less than 1,000 physicians. We will initially endeavor to hire a specialty sales force of approximately 60 sales representatives in anticipation of our potentially receiving FDA approval to support the commercial launch of our r-SNM System in the United States and we expect to grow our sales force over time and the number of our sales representatives at commercial launch will vary and may be higher depending on the duration of the PMA review process. We believe this focus will allow us to establish the necessary relationships and drive market penetration.

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

We also intend to promote broader awareness of SNM therapy for the treatment of OAB among patients and physicians, as well as awareness of the benefits and advantages of our r-SNM System. We plan to engage in awareness raising activities, highlighting the benefits of our r-SNM System in jurisdictions where we are approved to market. In addition, if and when approved in the United States, we intend to increase patient awareness of our r-SNM System through broad marketing initiatives.

While we have received regulatory approval in Europe, Canada, and Australia for OAB, FI, and UR, our main commercial priority is the United States where we expect to begin to commercialize and market our r-SNM System and generate revenue from product sales if and when approved by the FDA. We do expect to expend capital resources pursuing commercial operations in Europe, Canada, and Australia, the amount and timing of which will depend on a variety of factors, including the size of the developed market for SNM therapy, burdens to entry in such country or region, and other factors specific to certain respective countries and regions. In June 2018, we launched a limited commercial effort in Europe, where we currently have four dedicated sales representatives. Similar to the United States, we intend to replicate our strategy of targeting high-volume physicians and implant facilities.

Third-Party Coverage and Reimbursement

In the United States, we expect to derive nearly all of our 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, if and when approved, our r-SNM System and the associated procedures will be eligible to be considered 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, 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.

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 $13.1 million, $12.5 million, and $12.3 million, for the years ended December 31, 2015, 2016, and 2017, respectively. Our goals include introducing market differentiating 1.5T/3.0T MRI full body conditional labelling for our r-SNM System, reducing by half the number of IPG battery recharging sessions required for the IPG to remain charged for one full month, introducing compatibility features that would enable us to connect our IPG to an already implanted InterStim II lead, and expanding the suite of product solutions available for SNM therapy over time. Additionally, in the future, we intend to pursue regulatory approval for other indications in the United States in the future.

Manufacturing and Supply

We currently outsource the manufacture of all 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 after potential approval by the FDA.

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 compete as a third-line therapy in the market for the treatment of symptoms of OAB and FI. We consider our primary competition to be implantable SNM devices designed to treat OAB or FI. InterStim II is currently the only implantable SNM device approved for commercialization in the United States by the FDA, is approved for the treatment of the symptoms of OAB, including UUI and UUF, FI, and UR, and, together with its predecessor InterStim II, has been available to and used by physicians for over 20 years. Although we believe that our r-SNM System will offer significant benefits and we will have competitive strengths, our industry is evolving rapidly and we will continue to face significant competition. We expect Medtronic to launch new products or product improvements and release additional clinical evidence within the next few years, which

could include pursuing full body MRI and developing a rechargeable SNM device in the near future or significantly accelerating its existing plans to pursue any of these enhancements. If Medtronic were to develop a new device that is comparable to or more competitive than our r-SNM System in terms of size, battery life, patient and physician ease of operation, efficacy, cost and other features, the physician and patient community may prefer Medtronic's new device over ours due to a variety of factors, including familiarity with, and loyalty to, Medtronic. Additionally, we expect that Medtronic will engage in significant marketing and other efforts with physicians, many of whom they have long-term relationships with, to promote InterStim II and any other future SNM device Medtronic could develop and prevent, delay or reduce adoption of our r-SNM System. We believe other businesses, such as Nuvectra, may be in various stages of developing SNM devices designed to treat OAB or FI.

We also compete with other less invasive third-line treatments, such as BOTOX injections, a product sold by Allergan plc, and PTNS, as well as more invasive surgical treatment options, such as augmentation cystoplasty, which is a procedure that increases the size of the bladder and pharmaceutical companies that manufacture drugs for the treatment of OAB and FI.

We face competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. Our overall competitive position is dependent upon a number of factors, including:

- company, product and brand recognition;
- history of product use and physician familiarity with products and treatments;
- regulatory approvals and approved indications;
- product safety, reliability and durability;
- IPG 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. If and when our r-SNM System obtains FDA approval, competitors and other parties may also seek to impact our regulatory approval through the filing of citizen petitions or other similar documents, which could require costly and time-consuming responses to the FDA. Smaller 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

In order to remain competitive, we must develop and maintain protection for the proprietary aspects of our technologies. 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. The protection of intellectual property has been and remains a priority for us.

We own numerous issued patents and pending patent applications that relate to our r-SNM System and we licensed several issued patents and patent applications from AMF in 2013 pursuant to the License Agreement. As of September 30, 2018, we owned 17 issued U.S. patents and 20 issued foreign patents, and 17 pending U.S. patent applications and 59 pending foreign patent applications, and we licensed from AMF 30 issued U.S. patents and 38 issued foreign patents, and four pending U.S. patent applications and 28 pending foreign patent applications. Assuming all required fees and other charges are paid, issued patents owned or used by us will expire between 2023 and 2037. There is no active patent litigation involving any of our patents and we have not received any notices of patent infringement.

Pursuant to the License Agreement entered into in October 2013, AMF has certain rights to intellectual property that relates to the treatment of human tissue by the application of electrical energy and is reasonably necessary or useful to develop or commercialize the AMF Licensed Products owned by us, the Subject IP. Any Subject IP developed by us, whether solely or jointly with AMF, prior to our consummation of a qualified equity financing, would be owned by AMF and licensed to us as AMF IP under the License Agreement. In addition, AMF has certain rights to any Subject IP that is first created, conceived or reduced to practice subsequent to our consummation of a qualified equity financing as follows: (i) AMF will have exclusive license rights for patented improvements made by us to licensed AMF IP and (ii) AMF may optionally license from us Subject IP owned or controlled by us subject to a license fee, royalties, and use restrictions.

These provisions of the License Agreement have not affected our intellectual property portfolio to date. No Subject IP was developed prior to our consummation of our Series A preferred stock financing in March 2014, a financing constituting a qualified equity financing as used in the paragraph above. Further, we have not made improvements to Subject IP that are subject to the License Agreement and AMF has expressly declined in writing to exercise the option to license intellectual property from us.

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. While there is no active litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent infringement, 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 Matters” 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 selected 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 agreed to license to us the AMF IP to develop and commercialize the AMF Licensed Products. Any and all improvements to the AMF IP made by us will be owned by AMF and licensed to us under the License Agreement for purposes of making AMF Licensed Products. Pursuant to the License Agreement, AMF granted us a royalty-bearing, sublicensable (by written, executed agreements only, subject to the terms of the License Agreement) license, under the AMF IP, to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of (i) chronic pain in humans through the application of electrical energy to the nervous system, (ii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve, a nerve that interfaces with parasympathetic control of the heart, lungs and digestive tract and (iii) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system. We have the right to expand the field of use for the AMF Licensed Products to the (i) treatment of any condition (other than inflammatory conditions) in humans through the application of electrical energy to the vagus nerve or anywhere else in the body other than the vagus nerve, and (ii) 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.

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.

Pursuant to the License Agreement, we are obligated to pay a 4% royalty of all net revenue derived from the AMF Licensed Products if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case, subject to certain adjustments.

In 2017, we sold several of our r-SNM Systems as part of a one-time evaluation agreement with a hospital in Canada. As a result, we generated net revenue of $128,118 and recorded related royalties of $4,972 during the fiscal year ended December 31, 2017. No revenue was generated and no payments were made during the fiscal year ended December 31, 2016. In addition, beginning in 2018, we are required to pay AMF a minimum annual royalty, or the Minimum Royalty, payable quarterly if the royalty due is in excess of the Minimum Royalty, which will automatically increase each calendar year thereafter, subject to a maximum amount of $200,000 per year. We have accrued $37,500 as of June 30, 2018 toward AMF Minimum Royalties.

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF the greater of (i) the amount of the 4% royalty referred to above, and (ii) the Minimum Royalty for such calendar year beginning with 2018. We have 60 days to pay AMF this amount, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

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

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

The License Agreement was amended twice in February 2014, once in connection with our Series A preferred stock financing, in order to, among other things, include the field of the treatment of urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, within the scope of the licenses granted therein, an option under the License Agreement that required us to pay $1,000,000. In consideration for the inclusion of this field with the scope of the licenses granted in License Agreement, we issued AMF 50,000 shares of our Series A preferred stock.

As of June 30, 2018, AMF holds 888,000 shares of our common stock, 125,000 shares of our Series A preferred stock, and 771,161 shares of our Series B-1 preferred stock. John Petrovich, a member of our board of

directors, is the President, Chief Executive Officer, Senior Vice President, Business Development, and General Counsel of AMF.

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. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III de novo authorization—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another commercially available device that was cleared through the 510(k) process of the subject of de novo authorization.

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

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

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including 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. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, the FDA review process can often take up to several years. In some cases, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

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

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which may affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may require no clinical data or less extensive clinical data than the original PMA or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new supplement or PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Studies

Clinical studies are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to

submit an IDE application to the FDA, which must become effective prior to commencing human clinical studies. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the applicant that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical study to proceed under a conditional approval.

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

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

Post-market Regulation

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

- establishment, registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling;

- FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with health care providers;
- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of a cleared device, or approval of a supplement for certain modifications to PMA devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the new federal law and regulations requiring Unique Device Identifiers, 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
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

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

Our manufacturing processes will be required to comply with the applicable portions of the QSR, which covers the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices

intended for human use. The QSR also requires, among other things, maintenance of a device master record, device history file, and complaint files. As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our r-SNM System.

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

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

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

Regulation of Medical Devices in the EEA

Medical devices, other than active implantable medical devices, 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. Therefore, our external trial system, is subject to this 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 decides that rely on a source of electrical energy or any source of power other than that generated by the body, which are totally or partially introduced, either surgically or medically, into the human body and intended to remain after the procedure. We believe that our r-SNM System, or our internal product, qualifies as an AIMD and must therefore comply with the AIMD Directive, more specifically with the essential requirements it sets out at Annex I.

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

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

Under the AIMD Directive, manufacturers must demonstrate compliance with the essential requirements laid down in Annex I by undergoing a conformity assessment procedure. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed to ensure and declare that the products in question comply with the standards set out in Annex I of the AIMD Directive. In addition, a conformity assessment procedure requires the intervention of a Notified Body. Notified Bodies are separate entities that are authorized or licensed to perform such assessments by the governmental authorities of each EU Member State. Manufacturers of AIMDs must make an application to a Notified Body for an assessment of its technical dossiers and quality system. Alternatively, manufacturers can seek approval from the Notified Body that a representative sample of the products it has manufactured satisfies the requirements set out in the AIMD Directive and subsequently ensure and declare that all of its products conform to the standard of the approved sample. This is also known as “type approval.”

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

If satisfied that the AIMD or other medical device conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity (see above). The manufacturer may then apply the CE mark to the device, which allows the device to be legally placed on and traded within the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the product.

In order to demonstrate safety and effectiveness for their AIMDs and other medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive and Annex 7 to the AIMD Directive, as well as standards (if any) which may be imposed by national authorities of EEA states in addition to those set out in Annex X to the Medical Devices Directive and Annex 7 to the AIMD Directive, 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;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement; and
- necessity of testing performed in country by distributors for licensees.

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

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

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including stock, stock options, and the compensation derived through ownership interests.

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the United States Department of Health and Human Services issued regulations in July 1991, which the Department has referred to as “safe harbors.” These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published

intermittently since 1991. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Our arrangements with physicians, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (described below).

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

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

In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. Penalties for federal civil False Claim Act violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program. On May 20, 2009, the Fraud Enforcement Recovery Act of 2009, 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.

We intend to submit an equipment certification application for non-experimental use to the FCC for our r-SNM System. Any modifications to our r-SNM System after FCC approval, if obtained, may require new or

further FCC approval before we are permitted to import, market and sell a modified system, and it could take several months to obtain any necessary FCC approval. FCC approval has no impact on whether we will receive PMA approval.

Data Privacy and Security Laws

We are also subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act, 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 September 30, 2018, we had 72 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 lease this space under a lease that terminates on August 13, 2025. 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 intend to conduct the training of our sales team. We lease this space under a lease that terminates on October 31, 2019. 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

We are not currently subject to any material legal proceedings.

MANAGEMENT

Executive Officers, Directors, and Director Nominee

The following table sets forth certain information regarding our current executive officers, directors, and director nominees including their ages as of the date of this prospectus:

Name	Age	Position(s)
Executive Officers and Director		
Raymond W. Cohen	59	Chief Executive Officer, Director
Danny L. Dearen	55	President, Chief Financial Officer
Karen Noblett, M.D.	55	Chief Medical Officer
Prabodh Mathur	58	Chief Product Development Officer
Guangqiang (Jay) Jiang, Ph.D.	45	Chief Technology Officer
Alfred Ford	48	Chief Commercial Officer
John Woock, Ph.D.	35	Chief Marketing Officer
Michael V. Williamson	48	Senior Vice President, General Counsel
Rinda Sama	39	Chief Operating Officer
Non-Employee Directors and Director Nominee		
Raphaël Wisniewski	48	Chair of the Board of Directors
Erik Amble, Ph.D.	66	Director
Shahzad Malik, M.B. BChir	51	Director
John Petrovich	62	Director
Geoff Pardo	47	Director
Juliet Tammenoms Bakker	56	Director
Robert E. McNamara	61	Director Nominee

Executive Officers and Director

Raymond W. Cohen has served as our Chief Executive Officer and as a member of our board of directors since October 2013. Mr. Cohen has extensive international medical device experience, holding several Chair and Chief Executive Officer positions on the boards of both publicly listed and private life sciences companies in the United States and Europe. Since June 2013, Mr. Cohen has served as a member of the board of directors, Chair of the compensation committee, member of the audit committee and member of the nominating and corporate governance committee of Spectrum Pharmaceuticals, Inc., a developer and marketer of oncology and hematology drugs. From April 2016 to June 2017, Mr. Cohen served as a member of the board of directors and a member of the compensation and audit committees of Zurich-based LifeWatch AG, a manufacturer and marketer of ambulatory electrocardiogram services, which was acquired by Biotelemetry Inc. in July 2017. From June 2013 to December 2017, Mr. Cohen served as Chair of the board of directors of Lombard Medical, Inc., a manufacturer and marketer of abdominal aortic aneurysm stent graphs. Since May 2006, Mr. Cohen has served as a member of the board of directors, Chair of the audit committee, compensation committee and nominating committee, and since November 2013 as Chair of the board of directors, of BioLife Solutions, Inc., a developer, manufacturer and supplier of proprietary clinical grade cell and tissue hypothermic storage and cryopreservation freeze media for cells and tissues. From August 2010 to November 2012, Mr. Cohen served as Chief Executive Officer and as a member of the board of directors of Vessix Vascular, Inc., or Vessix, a developer of a novel renal denervation system used to treat uncontrolled hypertension, which was acquired by Boston Scientific Corporation. From 1997 to 2006, Mr. Cohen served as Chair and Chief Executive Officer of Cardiac Science, Inc., or Cardiac, a manufacturer of external automatic defibrillators. From 1982 to 1997, Mr. Cohen served in various sales and marketing positions for a number of medical device companies. In 2008, Mr. Cohen was named by AeA as the Private Company Life Science Chief Executive Officer of the Year. Mr. Cohen was named Entrepreneur of the Year in 2002 by the Orange County Business Journal and was a finalist for Ernst & Young’s Entrepreneur of the Year in the medical company category in 2004. Mr. Cohen holds a B.S. in Business

Management from the State University of New York at Binghamton. We believe Mr. Cohen's extensive experience in the medical device industry qualifies him to serve on our board of directors.

Danny L. Dearen has served as our President since August 2018 and our Chief Financial Officer since October 2013. From October 2013 to August 2018, Mr. Dearen served as our Chief Operating Officer. From July 2009 to October 2013, Mr. Dearen served as Chief Operating Officer and Chief Financial Officer of Vessix. From December 2004 to November 2008, Mr. Dearen served as Chief Financial Officer of Miraval Holding and from December 2000 to November 2004, he served as the Chief Financial Officer of Q3DM, which was acquired by Beckman Coulter. From October 1997 to October 2000, Mr. Dearen served as Chief Financial Officer of Fairbanks Systems Group. From July 1996 to October 1997, he served as Chief Financial Officer of ESI Software and from January 1995 to June 1996 Mr. Dearen served as Chief Financial Officer of Medication Delivery Devices, which was acquired by Baxter Healthcare. From June 1989 to December 1994, Mr. Dearen served as a Principal at Ventana Growth Funds. From July 1985 to July 1987, Mr. Dearen served as a certified public accountant in the healthcare group at Ernst & Young LLP. Mr. Dearen holds a B.B.A. in Accounting from Southern Methodist University and a Masters of Business Administration from Boston College.

Karen Noblett, M.D. has served as our Chief Medical Officer since October 2017. From January 2014 to September 2017, Dr. Noblett served as our physician advisor. From August 2014 to September 2017, Dr. Noblett served as Professor and Department Chair, OB/GYN, at the University of California, Riverside. From October 1998 to July 2014, Dr. Noblett served as Professor and Division Director at the University of California, Irvine. From July 1995 to June 1998, Dr. Noblett completed her fellowship in Female Pelvic Medicine and Reconstructive Surgery and from July 1991 to June 1995, she completed her residency in Obsterics and Gynecology at the University of California, Irvine. Dr. Noblett holds a B.A. in Biology from California State University, Fresno, an M.D. from the University of California, Irvine, and an M.S. in Research from the University of California, San Diego.

Prabodh Mathur, has served as our Chief Product Development Officer since May 2014. Mr. Mathur has extensive experience in developing implantable, interventional and external medical devices. Prior to joining our company, Mr. Mathur worked in research and development for Boston Scientific Inc. from December 2012 to May 2014. Prior to its acquisition by Boston Scientific Inc., Mr. Mathur served as the Chief Product Development Officer for Vessix from September 2010 to December 2012. Mr. Mathur holds a B.S. in Mechanical Engineering from the Indian Institute of Technology, Kanpur, India, and an M.S. in Mechanical Engineering from the Missouri University of Science and Technology.

Guangqiang (Jay) Jiang, Ph.D. has served as our Chief Technology Officer since October 2013. From October 2000 to October 2013, Mr. Jiang served as Vice President, Director of Research and Development, Director of Engineering and Engineering Manager of AMF. Mr. Jiang holds a B.S. in Mechanical Engineering and an M.E. in Welding Engineering from Tsinghua University, an M.S. in Materials Science and Engineering from Michigan Technological University and a Ph.D. in Biomedical Engineering from the University of Southern California, Los Angeles.

Alfred Ford has served as our Chief Commercial Officer since November 2017. From January 1997 to June 2017, Mr. Ford served as President and Chief Commercial Officer, General Manager, Vice President, Global Sales & Marketing, Vice President, Sales, Distribution Director, Regional Sales Manager and Territory Manager of Cardiac Science Corporation, the predecessor corporation of Cardiac. Mr. Ford holds a B.S. in Marketing and an M.S. in International Marketing from Saint Joseph's University.

John Woock, Ph.D. has served as our Chief Marketing Officer since June 2018. Prior to that time, Mr. Woock served as our Vice President, Global Marketing and Clinical Operations from January 2017 to May 2018 and our Vice President, Product Marketing from June 2014 to December 2016. Before working with our company, he was a postdoctoral fellow at the Stanford Biodesign Program at Stanford University from August 2013 to June 2014. From February 2010 to June 2013, Mr. Woock served as an engagement manager at

McKinsey & Company. From May 2003 to August 2003, Mr. Woock was a research fellow at Kentucky Spinal Cord Injury Research Center. Mr. Woock holds a B.S. in Biomedical Engineering from Washington University in St. Louis and a Ph.D. in biomedical engineering from Duke University.

Michael V. Williamson has served as our Senior Vice President and General Counsel since October 2013. Prior to joining our company, Mr. Williamson served as the General and Intellectual Property Counsel of Vessix from August 2011 to November 2012. Mr. Williamson holds a B.S. in Mechanical Engineering from California Polytechnic University, San Luis Obispo, and a J.D. from the John F. Kennedy Law School.

Rinda Sama has served as our Chief Operating Officer since August 2018. From May 2014 to August 2018, Mr. Sama served as our Vice President, Operations and Quality. From June 2011 to May 2014, Mr. Sama served as Director, Operations and Quality of Vessix. Mr. Sama holds a B.S. in Biomedical Engineering from Karnatak University Dharwad, an M.S. in Biomedical Engineering from the University of Southern California and an M.B.A from the University of California, Irvine.

Non-Employee Directors and Director Nominee

Raphaël Wisniewski has served as a member of our board of directors since March 2014 and the Chair of our compensation committee since July 2017 and as a member of our nominating and corporate governance committee since October 2018. Since 2001, Mr. Wisniewski has worked for Andera Partners, previously known as Edmond de Rothschild Investment Partners, a venture capital firm with extensive experience in the life science industry. Since 2006, Mr. Wisniewski has served as a Partner of Andera Partners. From 1999 to 2001 and from 1996 to 1999, Mr. Wisniewski served in the healthcare groups of the investment banking divisions of Goldman Sachs and Solomon Smith Barney, respectively, where he focused on investments in the pharmaceuticals, medical devices, biotechnology and services industries. Mr. Wisniewski holds a B.A. in History from Paris Sorbonne University, an M.S. in Business from HEC Paris and an M.S. Economics from IEP Paris. We believe Mr. Wisniewski's extensive experience in the life science industry qualifies him to serve on our board of directors.

Erik Amble, Ph.D. has served as a member of our board of directors since March 2014 and a member of our audit committee from July 2017 to October 2018. Since October 2018, Mr. Amble has served as a member of our nominating and corporate governance committee. Since July 2001, Mr. Amble has served as Chair of NeoMed Management (Jersey) Limited, the manager of NeoMed Innovation V L.P., a venture capital firm focused on supporting entrepreneurs and businesses in the healthcare industry. Mr. Amble holds a Ph.D. in Organic Chemistry from the University of Oslo and an M.Sc. in Management from the Graduate School of Business, Stanford University. We believe Mr. Amble's extensive experience in the healthcare industry qualifies him to serve on our board of directors.

Shahzad Malik, M.B. BChir has served as a member of our board of directors since December 2015 and a member of our compensation committee since July 2017. Since April 1999, Dr. Malik has served as a General Partner of Advent Life Sciences LLP. Since May 2017, Dr. Malik has served as a member of the board of directors and compensation committee of Iterum Therapeutics plc, a pharmaceutical company that focuses on developing anti-infectives for multi-drug resistant pathogens. Since February 2011, Dr. Malik has served as a member of the board of directors and compensation committee of Versartis, Inc., an endocrine-focused biopharmaceutical company. From March 2014 to June 2017, Dr. Malik served as a member of the board of directors and audit committee of Agenus Inc., a biotechnology company focused on immunotherapy. Dr. Malik holds an M.A. in Pre-Clinical Medicine from Oxford University and an M.B. BChir in Clinical Medicine from Cambridge University. We believe Dr. Malik's extensive experience in the pharmaceutical and biotechnology industry qualifies him to serve on our board of directors.

John Petrovich has served as a member of our board of directors since August 2013 and a member of our audit committee since July 2017. Since March 2010, Mr. Petrovich has served as the General Counsel, since

March 2011, as the Senior Vice President of Business Development, and since November 2017, as the President and Chief Executive Officer, of AMF. Since July 2017, Mr. Petrovich has served as the Chair of the board of directors of Medallion Therapeutics, Inc., a wholly owned subsidiary of AMF and a developer of a novel implantable drug delivery infusion pump. From November 2015 to July 2017, he served as the Chief Executive Officer and a member of the board of directors of Medallion Therapeutics, Inc. Mr. Petrovich holds a B.S. in Business Administration (Finance) from the University of Southern California and a J.D. from the University of California, Los Angeles, School of Law. We believe Mr. Petrovich's extensive experience in the medical research industry and the medical device industry qualifies him to serve on our board of directors.

Geoff Pardo has served as a member of our board of directors since July 2017 and as a member of our audit committee since October 2018. Mr. Pardo has served as a partner at Gilde Healthcare since 2011. Previously, he was a partner at Spray Venture Partners from 2004 to 2011. He also served as President and Chief Executive Officer of Facet Solutions, a spinal implant company focused on treating lumbar spinal stenosis, from 2007 until the company was sold to Globus Medical in 2011. He has also worked at Cardinal Partners as an Associate leading their investing activity in the medical device sector from 2001 to 2004. Mr. Pardo received a B.A. from Brown University and an M.B.A. from The Wharton School of Business. We believe Mr. Pardo's experience leading and managing a medical technology company, as well as his healthcare industry knowledge and his experience serving on the board of directors of other companies, qualifies him to serve on our board of directors.

Juliet Tammenoms Bakker has served as a member of our board of directors since March 2018 and as a member of our compensation committee and the Chair of our nominating and corporate governance committee since October 2018. Since January 2007, Ms. Tammenoms Bakker has served as a Managing Director of Longitude Capital Management Co., LLC, a healthcare venture capital firm. Ms. Tammenoms Bakker holds a B.Sc. from the College of Agriculture and Life Sciences at Cornell University and a M.P.A from the John F. Kennedy School of Government at Harvard University. We believe Ms. Tammenoms Bakker's extensive business and leadership experience qualifies her to serve on our board of directors.

Robert E. McNamara will serve as a member of our board of directors and as Chair of our audit committee upon completion of this offering. Since February 2018, Mr. McNamara has served as a member of the board of directors and audit committee of Xtant Medical Holdings, Inc., a publicly traded manufacturer and marketer of regenerative medical products and devices. Mr. McNamara previously worked at LDR Holdings/Spine, Inc., serving as its Executive Vice President from January 2013 to July 2016, and serving as its Chief Financial Officer from April 2012 to July 2016. From 2006 to 2009, Mr. McNamara served as a member of the board of directors and audit committee of Northstar Neurosciences, a publicly traded medical device company. From December 2004 to September 2008, Mr. McNamara was the Senior Vice President and Chief Financial Officer of Accuray, Inc., a publicly traded medical device manufacturer. In addition, Mr. McNamara has served as the Senior Vice President and Chief Financial Officer of Somnus Medical Technologies and the Chief Financial Officer for Target Therapeutics, Inc., each publicly traded companies. Mr. McNamara is the former Mayor of Menlo Park, California. Mr. McNamara holds a B.S. in Accounting from the University of San Francisco and an M.B.A. in Finance from The Wharton School of Business. We believe that Mr. McNamara's extensive experience as an executive and director in the medical device industry and his prior service as a senior-level executive in medical device companies qualifies him to serve on our board of directors.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Board Composition and Election of Directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members and is expected to be increased to eight members upon completion of this offering.

The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our Voting Agreement, which is defined below. Under the terms of our Voting Agreement, the stockholders who are party to the voting agreement have agreed to vote their respective shares to elect: (i) one director designated by BioDiscovery 4 FCPR, currently Raphaël Wisniewski, (ii) one director designated by NeoMed Innovation V, L.P., currently Erik Amble, Ph.D., (iii) one director designated by AMF, currently John Petrovich, (iv) one director designated by Advent Life Sciences LLP, currently Shahzad Malik, M.B. BChir, (v) one director designated by Coöperatieve Gilde Healthcare IV U.A., currently Geoff Pardo, (vi) one director designated by Longitude Venture Partners III, L.P., currently Juliet Tammenoms Bakker, and (vii) one director elected by at least two-thirds of the outstanding shares of our preferred stock and a majority of the outstanding shares of our common stock, each voting as a separate class, who must be our Chief Executive Officer, currently Raymond W. Cohen. Pursuant to the Voting Agreement, all shares to be voted as referenced above assumes the exchange of all exchange shares pursuant to the Share Exchange Agreement, which is defined below.

Following this offering, no stockholder will have any special rights regarding the election or designation of members of our board of directors. Our current directors will continue to serve as directors until their resignation, their removal, or a successor is duly elected.

Director Independence

Upon the completion of this offering, we anticipate that our common stock will be listed on the Nasdaq Global Market. Under the Nasdaq Marketplace Rules, independent directors must compose a majority of a listed company's board of directors within 12 months after its initial public offering. In addition, the Nasdaq Marketplace Rules require that, subject to specified exceptions and phase in periods following its initial public offering, each member of a listed company's audit, compensation, nominating and governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, or Rule 10A-3. Under the Nasdaq Marketplace Rules, a director will qualify as an "independent director" if, among other criteria in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of our audit committee, our board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, or (ii) be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors determined that all directors, other than Mr. Cohen, are "independent directors" as defined under the Nasdaq Marketplace Rules. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section entitled "Certain Relationships and Related Party Transactions." In addition to determining whether each director satisfies the director independence requirements set forth in the Nasdaq Marketplace Rules, in the case of members of our audit committee and our compensation committee, our board of directors has also made an affirmative determination that such members also satisfy separate independence requirements and current standards imposed by the SEC Rule 10A-3, and the Nasdaq Marketplace Rules for audit committee members and by the SEC, the Nasdaq Marketplace Rules, and the Internal Revenue Service, or IRS, for compensation committee members.

Board Leadership Structure

As a general policy, we believe that separation of the positions of Chair of our board of directors and our Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole. As such, Mr. Cohen, our Chief Executive Officer, does not presently serve, and will not serve, as our Chair of the board of directors following this offering. However, we will reevaluate this policy from time to time and may in the future elect to combine the roles of Chief Executive Officer and Chair of our board if our board of directors believes it is in the best interest of our stockholders.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is overseeing our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee, compensation committee and nominating and corporate governance committee support our board of directors in discharging its oversight duties and address risks inherent in their respective areas. We believe this division of responsibilities is an effective approach for addressing the risks we face and that our board leadership structure supports this approach. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee. Each committee operates under a written charter that has been approved by our board of directors. Prior to the completion of this offering, copies of each committee's charter will be posted on the Investor Relations section of our website, which is located at 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 common stock. Each committee has the composition and responsibilities described below. Our board of directors may from time to time establish other committees.

Audit Committee

Our audit committee consists of Geoff Pardo and John Petrovich. Robert E. McNamara will be appointed Chair of our audit committee upon consummation of this offering. Our board of directors has determined that each of the members of our audit committee satisfies the Nasdaq Marketplace Rules, Rule 10A-3, and SEC independence requirements. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent registered public accounting firm and determining whether to retain our existing independent registered public accounting firm or engage a new independent registered public accounting firm;

- reviewing and approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;

- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent registered public accounting firm and management;

- reviewing with our independent registered public accounting firm and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;

- reviewing and approving related party transactions;

- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented; and

- reviewing and evaluating the performance of our audit committee, including compliance of the committee with its charter.

Our board of directors has determined that Mr. McNamara qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Marketplace Rules. In making this determination, our board has considered Mr. McNamara's extensive financial experience and business background. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Compensation Committee

Our compensation committee consists of Raphaël Wisniewski, who is the Chair of the committee, Shahzad Malik, M.B. BChir, and Juliet Tammenoms Bakker. Our board of directors has determined that each of the members of our compensation committee satisfies the Nasdaq Marketplace Rules independence requirements and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The functions of this committee include, among other things:

- reviewing, and making recommendations to our full board of directors annually regarding, the corporate goals and objectives applicable to the compensation of our chief executive officer, evaluate at least annually our chief executive officer's performance in light of those goals and objectives, and recommend to our board of directors our chief executive officer's compensation level based on our compensation committee's evaluation, including discretionary bonuses and cash incentive awards;

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to our full board of directors regarding), our overall compensation strategy and policies;

- reviewing, and making recommendations to our full board of directors annually regarding, the compensation, discretionary bonus, cash incentive awards, the performance goals and objectives relevant to the compensation, and other terms of employment of our executive officers;

- reviewing, and approving (or if it deems appropriate, making recommendations to our full board of directors regarding), the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;

- reviewing, and making recommendations to our full board of directors regarding, the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

- reviewing, and making recommendations to our full board of directors regarding, director compensation; and
- preparing the compensation report that the SEC requires in our annual proxy statement.

Nominating and Corporate Governance Committee

Our nominating and corporate government committee consists of Juliet Tammenoms Bakker, who is the Chair of the committee, Erik Amble, Ph.D., and Raphaël Wisniewski. Our board of directors has determined that each of the members of our nominating and corporate governance committee satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- identifying, reviewing, evaluating, and recommending candidates to serve on our board of directors and committees of our board of directors consistent with criteria approved by our board of directors;
- evaluating director performance on our board of directors and committees of our board of directors and determining whether continued service on our board and such committees is appropriate;
- evaluating, nominating, and recommending individuals for membership on our board of directors; and
- evaluating nominations by stockholders of candidates for election to our board of directors.

Compensation Committee Interlocks and Insider Participation

During our fiscal year ended December 31, 2017, our compensation committee was comprised of Messrs. Wisniewski and Pardo, and Dr. Malik. As of October 2018, our compensation committee consists of Messrs. Wisniewski and Pardo, and Ms. Bakker. None of the current or previous members of our compensation committee is, or ever has been, an officer or employee of ours, nor had any relationship requiring disclosure by us under any paragraph of Item 404 of Regulation S-K of the SEC. None of our executive officers currently serves on our compensation committee or a board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Code of Conduct

Prior to the completion of this offering, we will adopt a code of conduct that will apply to all of our employees, officers and directors, including those officers responsible for financial reporting, which will be available on our website, which is located at www.axonicsmodulation.com. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website. 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 common stock.

EXECUTIVE COMPENSATION

Our named executive officers, which consist of our principal executive officer and our two other most highly compensated officers for our fiscal year ended December 31, 2017, are:

- Raymond W. Cohen, Chief Executive Officer;
- Danny L. Dearen, President and Chief Financial Officer; and
- Karen Noblett, M.D., Chief Medical Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

As noted above, we are an "emerging growth company," as that term is used in the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act.

Summary Compensation Table

The following table sets forth total compensation paid to our named executive officers for our fiscal year ended December 31, 2017.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Raymond W. Cohen *Chief Executive Officer*	2017	430,000	164,480	10,800	605,280
Danny L. Dearen *President and Chief Financial Officer*	2017	315,000	95,884	10,800	421,684
Karen Noblett, M.D. *Chief Medical Officer*	2017	87,500(1)	38,718	76,346	202,564

(1) Dr. Noblett's annual salary is $350,000. The amount shown reflects the salary earned from her commencement as a named executive officer on October 2, 2017 through December 31, 2017. Before October 2, 2017, Dr. Noblett provided services to us as a consultant.

(2) Represents the aggregate grant date fair value of option awards granted during 2017, computed in accordance with FASB ASC Topic 718. For Dr. Noblett, this includes the aggregate grant date fair value of the option awards granted to her on May 23, 2017, July 5, 2017, and August 25, 2017, in each case, before she became a named executive officer. See Note 5 to our consolidated financial statements included elsewhere in the prospectus for a discussion of the assumptions we made in determining the grant date fair value of our option awards.

(3) Reflects company matching contributions to our 401(k) plan and for Dr. Noblett, tuition reimbursement in the amount of $31,346 and consulting fees of $45,000 paid to her in 2017 before she became a named executive officer on October 2, 2017.

Annual Base Salary

The annual base salaries of our named executive officers will generally be determined and approved at the beginning of each year, or later if in connection with the commencement of employment of the executive, by

our board of directors. Each named executed officer's initial base salary is provided in his or her employment agreement. As reflected below, the annual base salaries for Mr. Cohen and Dr. Noblett did not change at the beginning of 2018. Mr. Dearen's annual base salary for 2018 increased by $35,000 compared to his annual base salary for 2017 because of increased individual responsibilities and strong performance.

Name	2018 Base Salary
Raymond W. Cohen	$430,000
Danny L. Dearen	$350,000
Karen Noblett, M.D.	$350,000

Bonus Compensation

We do not currently have an established bonus plan or policy for our executive officers. From time to time, our board of directors or compensation committee may approve bonuses for our named executive officers based on individual performance, company performance or as otherwise determined appropriate in their sole discretion. None of our named executive officers received an annual cash bonus for their performance in 2017.

Equity Compensation Plan Awards

Our equity-based compensation awards are designed to align the interests of our stockholders with those of our employees and consultants, including our named executive officers. Our board of directors is responsible for approving equity grants.

We have historically used stock options as the primary incentive for long-term compensation to our named executive officers because the officers are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, which exercise price is set at the fair market value of our common stock at the date of grant. We may grant equity awards at such times as our board of directors determines to be appropriate. Our executives generally are awarded an initial grant in the form of a stock option in connection with their commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to this offering, we granted all equity awards pursuant to the 2014 Plan. Following this offering, we will no longer grant awards under the 2014 Plan and all future grants of equity compensation awards will be under the 2018 Plan. The terms of our equity plans are described below under "—Equity Compensation Plans."

Stock options granted to our named executive officers generally become exercisable over a four-year period, with one-fourth becoming exercisable on the vesting commencement date and the remaining three-fourths becoming exercisable in equal monthly installments over the 36 months after the first anniversary of the vesting commencement date, subject to continuous service. Prior to becoming a named executive officer, Dr. Noblett received stock options that become exercisable over a three-year period, with one-fourth of the options becoming exercisable on the vesting commencement date and the remaining three-fourths becoming exercisable in equal monthly installments over the 36 months after the vesting commencement date, subject to continuous service through each vesting date.

Retirement Plans

We maintain a 401(k) retirement savings plan in which our named executive officers are eligible to participate on the same basis as our other full-time employees. We currently make matching contributions under our 401(k) plan of 100% on the first 3% of the participant's compensation and 50% between 3% and 5% of compensation, subject to IRS limits. The terms of our 401(k) plan are described below under "—401(k) Plan."

Health and Welfare Benefits and Perquisites

Our named executive officers are eligible to participate in our employee benefit plans and programs, including medical, dental, vision, group life, disability and accidental death and dismemberment insurance, in each case, on the same basis as our other full-time employees. Except for tuition reimbursement to Dr. Noblett, we do not provide any perquisites or personal benefits (as described under applicable SEC rules) to our named executive officers.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes, for each of our named executive officers, the number of outstanding equity awards held on December 31, 2017.

		Option Awards(1)					Stock Awards(5)		
			Number of Securities Underlying Unexercised Options						
Name	Grant Date	Vesting Commencement Date(2)(3)	Exercisable (#)	Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of shares of stock that have vested (#)	Number of shares of stock that have not vested (#)	Market value of shares of stock that have not vested ($)
Raymond W. Cohen	03/14/2014	—	—	—	—	—	119,020	—	
Chief Executive Officer	01/15/2016	—	—	—	—	—	172,266	172,266	244,044
	05/23/2017	—	—	—	—	—	17,304	51,911	73,540
	07/05/2017	—	—	—	—	—	10,356	31,068	44,013
	08/25/2017	—	—	—	—	—	18,840	56,522	80,072
Danny L. Dearen	03/14/2014	—	—	—	—	—	79,395	—	
President and Chief Financial Officer	01/15/2016	01/15/2016	68,691	68,690(2)(3)	0.98	01/15/2026	—	—	
	05/23/2017	05/23/2017	9,705	29,112(2)(3)	1.32	05/23/2027	—	—	
	07/05/2017	07/05/2017	6,136	18,404(2)(3)	1.32	07/05/2027	—	—	
	08/25/2017	07/21/2017	11,162	33,482(2)(3)	1.42	08/25/2027	—	—	
Karen Noblett, M.D.	10/01/2015	10/01/2015	5,700	1,500(4)	0.97	10/01/2025	—	—	
Chief Medical Officer	01/15/2016	01/15/2016	7,000	2,600(4)	0.98	01/15/2026	—	—	
	05/23/2017	05/23/2017	277	424(4)	1.32	05/23/2027	—	—	
	07/05/2017	07/05/2017	138	252(4)	1.32	07/05/2027	—	—	
	08/25/2017	07/21/2017	251	459(4)	1.42	08/25/2027	—	—	
	10/30/2017	—	—	—	—	—	6,190	18,568	26,304
	11/15/2017	—	—	—	—	—	3,740	11,222	15,898

(1) All of the options have been granted under the 2014 Plan. The terms of the 2014 Plan are described below under "—Equity Compensation Plans."

(2) One-fourth of the options vested on the vesting commencement date and the remaining three-fourths vest in equal monthly installments over the three years after the first anniversary of the vesting commencement date, subject to continuous service through each vesting date.

(3) This option award is subject to an early exercise provision and is immediately exercisable in exchange for restricted shares.

(4) One-fourth of the options vested on the vesting commencement date and the remaining three-fourths vest in equal monthly installments over the three years after the vesting commencement date, subject to continuous service through each vesting date.

(5) These are restricted shares received upon the early exercise of stock options, which shares are subject to the same vesting terms as the underlying options.

Equity Compensation Plans

2018 Omnibus Incentive Plan

In connection with this offering, we have adopted, and our stockholders have approved, the 2018 Plan, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2018 Plan are summarized below. On October 16, 2018, our board of directors and stockholders approved and adopted the 2018 Plan effective October 18, 2018. The 2018 Plan is scheduled to terminate October 18, 2028, but may be terminated earlier by our board of directors, as described below.

Stock Awards. The 2018 Plan provides for the grant of options intended to qualify as "incentive stock options" as defined in Section 422 of the Code, or ISOs, nonstatutory stock options, or NSOs, stock appreciation rights, or SARs, restricted stock awards, restricted stock units, or RSUs, and other stock-based awards. ISOs may be granted only to employees. All other awards may be granted to our and our affiliates' employees, non-employee directors, consultants and other service providers.

Administration, Amendment and Termination. The 2018 Plan is administered by our board of directors or a committee of our board of directors designated by our board of directors to administer the 2018 Plan. Our board of directors has retained the right to exercise the authority of any committee that it appoints to administer the 2018 Plan to the extent consistent with applicable law and the applicable requirements of any stock exchange.

Subject to the terms of the 2018 Plan, the plan administrator has the authority to (i) grant and amend awards, which includes determining the type, form, terms and conditions and number of shares subject to any award, (ii) interpret any provision of the 2018 Plan, any award or any award agreement and (iii) make all determinations and decisions necessary for the administration of the 2018 Plan. All determinations and decisions by the plan administrator under the 2018 Plan are in its sole discretion and are final and binding.

Securities to be Offered. The 2018 Plan provides for awards based on shares of our common stock. Subject to adjustment as described below, the total number of shares authorized to be awarded under the 2018 Plan may not exceed 4,540,019, which includes the number of shares authorized and available for issuance under the 2014 Plan as of the date the 2018 Plan became effective.

Any award settled in cash will not be counted as issued shares for any purpose under the 2018 Plan. If any award expires, or is terminated, surrendered or forfeited, the unissued shares covered by the award will again be available for the grant of awards. If shares issued pursuant to the 2018 Plan are repurchased by, or are surrendered or forfeited to our company, at no more than cost, those shares will again be available for the grant of awards. If shares issuable upon exercise, vesting or settlement of an award or shares owned by a grantee are surrendered or tendered to our company in payment of the purchase price of an award or any taxes required to be withheld for an award, those surrendered or tendered shares will again be available for the grant of awards.

Substitute awards will not be counted against the number of shares available for the grant of awards under the 2018 Plan.

Eligibility. Eligibility to participate in the 2018 Plan is limited to our and our affiliates' employees, officers, non-employee directors, and consultants as determined from time to time by the plan administrator.

Stock Options. The 2018 Plan provides for the grant of options to purchase shares of common stock at exercise prices, and subject to terms, conditions and limitations, determined by the plan administrator and set forth in an option agreement delivered to the optionee. Options may include the option for a grantee who is employed to elect to exercise the option prior to the option becoming fully vested and any other restrictions our board of directors deems appropriate. Any unvested shares so purchased will remain subject to a repurchase option in favor of us.

An option that the plan administrator intends to be an ISO may be granted only to our employees and will be subject to and construed consistently with the requirements of Section 422 of the Code. An option that does not qualify as an ISO is referred to as a NSO.

Stock Appreciation Rights. The 2018 Plan provides for the grant of SARs, which may be awarded either alone or in tandem with, or as a component of, other awards. The applicable award agreement will include information about the terms and conditions under which a SAR will be exercisable, including any performance requirements. A SAR confers on the participant a right to receive, upon exercise, a payment of the excess of (i) the fair market value of one share of our stock on the date of exercise over (ii) the grant price of the SAR as determined by the plan administrator (which will be equal to at least fair market value on the grant date).

Restricted Stock Awards. The 2018 Plan provides for the grant of restricted stock awards. In general, a restricted stock award is an award of actual shares of common stock issued in the participant's name that are subject to certain vesting requirements and that we may hold until the applicable vesting date, at which time the shares are released to the participant. The plan administrator will determine the terms and conditions of any restricted stock award, which will be set forth in the restricted stock agreement delivered to the participant. A restricted stock award holder will have all the rights of a stockholder with respect to such shares, including voting and dividend rights, subject, however, to the restrictions and conditions specified in the restricted stock agreement.

Restricted Stock Units. The 2018 Plan provides for the grant of RSUs. An RSU represents the right to receive one share of common stock upon the applicable vesting date, but no share is actually issued until vesting. An RSU may be settled in cash rather than stock to the extent provided in the applicable award agreement. The plan administrator will determine the terms and conditions of any RSUs granted under the 2018 Plan. In general, a holder of RSUs will not have any rights of a stockholder but the plan administrator may provide that the holder is entitled to receive dividend equivalent rights.

Stock-Based Performance Awards. The 2018 Plan provides for the grant of awards based on various performance conditions as may be specified by the plan administrator. Settlement of performance awards may be in cash, shares, other awards or other property, in the discretion of the plan administrator. The plan administrator may reduce the amount of a settlement otherwise to be made in connection with performance awards.

Other Stock-Based Awards. The plan administrator may grant other stock-based awards, either alone or in addition to or in conjunction with other awards under the 2018 Plan, based upon the common stock, having terms and conditions as the plan administrator may determine.

Transferability of Awards. Unless authorized in the applicable award agreement, a participant may not assign or transfer an award under the 2018 Plan, except by will or as permitted under the laws of descent and distribution. During a participant's lifetime, only the participant personally (or his or her personal representative) may exercise rights under the 2018 Plan.

Rights as Stockholder. Unless an applicable award agreement states otherwise, a 2018 Plan participant will have no rights as a stockholder with respect to any shares covered by an award until he or she becomes the record holder of the shares.

Withholding for Payment of Taxes. We may deduct from payments of any kind otherwise due to a 2018 Plan participant any federal, state or local taxes of any kind required by law to be withheld in connection with the vesting of or other lapse of restrictions applicable to an award or upon the issuance of any shares of stock upon the exercise of an option or pursuant to an award.

Effect of Certain Transactions. If (i) the number of outstanding shares of our common stock is increased or decreased or the shares are changed into or exchanged for a different number or kind of shares or other securities of our company on account of any recapitalization, reclassification, stock split, reverse split, combination of shares, exchange of shares, stock dividend or other distribution payable in capital stock, or other increase or decrease in shares effected without receipt of consideration by our company or (ii) there is a spin-off, split-up, extraordinary cash dividend or other distribution of assets by our company, then (a) the number and kind

of shares for which grants of 2018 Plan awards may be made, (b) the number and kind of shares for which outstanding awards may be exercised or settled and (c) the performance goals relating to outstanding awards, will all be equitably adjusted. In addition, in the event of any increase or decrease in the number of outstanding shares or other transaction described in clause (ii) above, the number and kind of shares for which 2018 Plan awards are outstanding and the option price per share of outstanding stock options will be equitably adjusted.

Unless otherwise provided in an award agreement, in the event of a corporate transaction (i.e., a reorganization, merger, statutory share exchange, consolidation, sale of all or substantially all of our company's assets, acquisition of assets or stock of another entity by our company, or other corporate transaction involving our company or any of our affiliates), the 2018 Plan and awards under it will continue in effect in accordance with their terms, except that after a corporate transaction either (i) each outstanding award will be treated as provided for in the corporate transaction agreement or (ii) if not covered in the corporate transaction agreement, each grantee will be entitled to receive for each share of common stock under the grantee's awards (upon exercise or payment or transfer in respect of those awards), the same consideration that each of our common stockholders was entitled to receive in the corporate transaction for one share, except that such consideration will remain subject to all of the terms and conditions (including performance criteria) that were applicable to the awards before the corporate transaction. Treatment of 2018 Plan awards upon a corporate transaction may include cancellation and liquidation of stock options and SARs (including for $0 if the options or SARs are underwater at the time of the corporate transaction).

Change in Control. In the event of a "change in control" (as defined in the 2018 Plan), either of the following provisions will apply to 2018 Plan awards outstanding at the time, depending on whether, and the extent to which, awards are assumed, converted or replaced by the resulting entity in the change in control (and unless otherwise provided in the applicable award agreement):

(1) If awards are not assumed, converted or replaced by the resulting entity in the change in control, then those awards will become fully exercisable and all restrictions on the awards will lapse, except for performance awards, for which the target payout opportunities attainable will be deemed to have been fully earned as of the change in control based upon the greater of (a) an assumed achievement of all relevant performance goals at the "target" level or (b) the actual level of achievement of all relevant performance goals against target as of our fiscal quarter end preceding the change in control.

(2) If awards are assumed, converted or replaced by the resulting entity in the change in control, if, within 24 months after the change in control, the grantee is involuntarily terminated or resigns for good reason, if permitted under the applicable award agreement, the grantee's awards will become fully exercisable and all restrictions on the awards will lapse, except for performance awards, for which the target payout opportunities attainable will be deemed to have been fully earned as of the involuntary termination based upon the greater of (a) an assumed achievement of all relevant performance goals at the "target" level, or (b) the actual level of achievement of all relevant performance goals against target as of our fiscal quarter end preceding the change in control.

Amendment and Termination. The plan administrator may amend, suspend or terminate the 2018 Plan as to any awards that have not been made. No alteration, amendment, suspension or termination of the 2018 Plan may, without participant consent, materially impair rights or obligations under any outstanding award. The plan administrator may amend, modify or supplement the terms of any outstanding award, including modification of awards to foreign nationals or individuals who are employed outside the United States to recognize differences in local law, tax policy or custom.

2014 Stock Incentive Plan

Our board of directors originally adopted the 2014 Plan on March 12, 2014 and our stockholders approved the 2014 Plan on the same date. The 2014 Plan was amended effective December 4, 2015, April 19, 2017, and March 29, 2018, to increase the number of shares available for issuance pursuant to plan awards. On and following effectiveness of the 2018 Plan on October 18, 2018, no further grants will be made under the 2014 Plan.

Stock Awards Eligibility. The 2014 Plan provides for the grant of ISOs, NSOs, and restricted stock. Only employees of our company or of an affiliate (including officers of our company and members of our board of directors if they are employees of an affiliate) are eligible to receive ISOs under the 2014 Plan. All other awards may be granted to our and our affiliates' employees, non-employee directors, consultants and other service providers.

Administration, Authority of Plan Administrator. The 2014 Plan is administered by our board of directors or a committee of our board of directors designated in whole or in part to administer the 2014 Plan.

Subject to the terms of the 2014 Plan or by any applicable law, the plan administrator has the authority to, among other things, (i) determine which persons will receive an award, (ii) grant and amend awards, which includes determining the type, form, terms and conditions and number of shares subject to any award, (iii) interpret any provision and amend any rules of the 2014 Plan, any award or any award agreement, and (iv) make all determinations and decisions necessary for the administration of the 2014 Plan. All determinations and decisions by the plan administrator under the 2014 Plan are in its sole discretion and are final and binding.

Securities to be Offered. The 2014 Plan provides for awards based on shares of our common stock. Subject to adjustment as described below, the total number of shares authorized to be awarded under the 2014 Plan may not exceed 3,178,593. As of June 30, 2018, there were 37,971 shares available for issuance under the 2014 Plan. Shares subject to awards that have been terminated and shares initially subject to an award but reacquired by us will again be available for grant under the plan.

Stock Options. The 2014 Plan provides for the grant of options to purchase shares of common stock at exercise prices, and subject to terms, conditions and limitations, determined by the plan administrator and set forth in an option agreement delivered to the optionee.

The exercise price per share of common stock subject to each option will be determined by the plan administrator and will not be less than 100% of the fair market value per share of common stock on the date the option is granted. The option term will be set by the plan administrator but no option may be exercisable more than 10 years after the date of grant. An option that the 2014 Plan administrator intends to be an ISO will be subject to and be construed consistently with the requirements of Section 422 of the Code. An option that does not qualify as an ISO is referred to as a "nonstatutory option."

Restricted Stock Awards. The 2014 Plan provides for the grant of restricted stock awards. In general, a restricted stock award is an award of actual shares of common stock issued in the participant's name. The restricted stock agreement will provide the date or dates, the performance criteria or objectives which must be achieved, and any other conditions on which the restricted stock may vest.

The plan administrator will determine the terms and conditions of any restricted stock award, which will be set forth in the restricted stock agreement delivered to the participant. A restricted stock award holder will have all the rights of a stockholder with respect to such shares, including voting and dividend rights, subject, however, to the restrictions and conditions specified in the restricted stock agreement.

Promissory Note. Certain of the of the stock option award agreements provide the optionee the right to exercise his or her options through and subject to the terms of a secured full recourse promissory note as may be

made available to certain eligible employees by the Company under the 2014 Plan. An optionee is required to concurrently execute and deliver a pledge agreement, should the optionee exercise the option for the purchase of the shares underlying the option using the full recourse promissory note.

Repurchase Right. Should a participant's service with the company terminate for any reason, the participant's option agreement or restricted stock agreement may provide our company the right, at the discretion of the plan administrator, to repurchase shares of common stock acquired pursuant to the exercise of an option or pursuant to a restricted stock agreement. For vested options or shares, the repurchase price will equal the fair market value per share of common stock as of the termination of employment. For unvested options or shares, the repurchase price will equal either fair market value per share of common stock as of the termination of employment or the exercise price, in the case of options, or the original purchase price paid per share (if any), in the case of restricted stock.

Transferability of Awards. A participant may not sell, assign, transfer or pledge an award under the 2014 Plan, except as otherwise provided by the plan administrator in an option agreement or restricted stock agreement or by will or as permitted under the laws of descent and distribution. During a participant's lifetime, only the participant personally may exercise rights under the 2014 Plan. The plan administrator may grant nonstatutory options that may be transferred to a revocable trust or as otherwise permitted under Rule 701 of the Securities Act.

Rights as Stockholder. An optionee or permitted transferee of an option will have no rights or privileges as a stockholder with respect to any shares covered by an option until such option has been duly exercised and shares purchased upon such exercise have been issued to such person.

Withholding for Payment of Taxes. We may deduct from payments of any kind otherwise due to a 2014 Plan participant any federal, state or local taxes of any kind required by law to be withheld in connection with the vesting of or other lapse of restrictions applicable to an award or upon the issuance of any shares of stock upon the exercise of an option or pursuant to an award.

Effect of Certain Transactions. If the number of outstanding shares of our common stock is increased or decreased or the shares are changed into or exchanged for a different number or kind of shares or other securities of our company on account of any recapitalization, reclassification, stock split, reverse split, combination of shares, stock dividend, or other change in the capital structure of our company then appropriate adjustment will be automatically made to (i) the aggregate number and kind of shares subject to this plan, (ii) the number and kind of shares and the exercise price or purchase price per share subject to outstanding award agreements, and (iii) the limits on the number of shares subject to the plan, all in order to preserve, as nearly as practical, but not to increase, the benefits to participants.

Change in Control. In the event of a "change in control" (as defined in the 2014 Plan), all outstanding stock options will fully vest automatically, effective immediately prior to the change in control. Additionally, our right to repurchase shares of common stock pursuant to an award granted under the 2014 Plan will automatically terminate immediately prior to the consummation of a change in control and the shares subject to those terminated repurchase rights will immediately vest in full.

Amendment and Termination. Our board of directors may alter, amend, suspend or terminate the 2014 Plan as our board of directors may deem advisable. No alteration, amendment, suspension or termination of the 2014 Plan may, without participant consent, substantially affect or impair the rights of any participant under an outstanding award agreement, or cause the 2014 Plan or any award granted thereunder, to violate Code Section 409A.

Our board of directors may alter or amend the 2014 Plan to comply with requirements under the Code relating to ISOs or other types of options that give optionees more favorable tax treatment than that applicable to

options granted under this plan as of the date of its adoption. Upon any such alteration or amendment, any outstanding award granted under the 2014 Plan may, if the plan administrator so determines and if permitted by applicable law, be subject to the more favorable tax treatment afforded to a participant pursuant to such terms and conditions.

Unless terminated beforehand, the 2014 Plan will terminate on the 10th anniversary of March 12, 2014 and no awards may be granted under the 2014 Plan thereafter, but outstanding award agreements will continue in effect in accordance with their respective terms.

Potential Payments upon Termination or Change in Control

In our employment agreements with Mr. Cohen, Mr. Dearen and Dr. Noblett, we have agreed to provide severance equal to 12 months of base pay for Mr. Cohen and Mr. Dearen and 6 months of base pay for Dr. Noblett. See "—Agreements with our Named Executive Officers" immediately below.

Agreements with Our Named Executive Officers

Below are descriptions of the key terms of our employment agreements with Mr. Cohen, Mr. Dearen and Dr. Noblett. The agreements provide for employment terms and set forth the officer's base salary at the time of hire, other compensation and benefits and severance benefits on a qualifying termination of employment. Additionally, the employment agreements contain proprietary inventions and confidential information provisions. We intend to enter into new employment agreements with each of our named executive officers after the completion of this offering.

Raymond W. Cohen

We entered into an employment agreement with Mr. Cohen in May 2014 under which Mr. Cohen will serve as our Chief Executive Officer. The agreement provides that Mr. Cohen's term as our Chief Executive Officer will run from May 22, 2014 to July 1, 2019, sets forth his initial base salary of $360,000, which will be reviewed on an annual basis, and sets forth his eligibility to receive such medical coverage and other benefits available to senior executives. Mr. Cohen's employment may terminate earlier than July 1, 2019, upon Mr. Cohen's death or disability (meaning he is unable to perform his duties for more than 26 substantially consecutive weeks in any 12-month period). We may also terminate Mr. Cohen's employment for cause (which includes acts that would constitute misappropriation, embezzlement or fraud, materially and adversely impact our business or reputation, conviction of, or entering into a plea of no contest of, a felony, and any breach of the agreement that remains uncured after providing notice to Mr. Cohen of the breach) at any time, and we may terminate Mr. Cohen without cause upon 30 days' prior written notice. The agreement covers stock options granted to Mr. Cohen to purchase 119,020 shares of common stock, which will accelerate and vest in full in the event there is a change in control before or within 90 days following termination of Mr. Cohen's service. These options have been exercised by Mr. Cohen in accordance with their terms. Mr. Cohen's employment agreement also includes proprietary inventions and confidential information provisions.

Further, under the employment agreement, if Mr. Cohen's employment terminates prior to July 1, 2019 by reason of death or disability, Mr. Cohen or his estate will be eligible to receive severance equal to 12 months of base salary, conditioned upon his or his agent's execution of a waiver and release agreement. If we terminate Mr. Cohen's employment prior to July 1, 2019 without cause, including after a change in control, or if he terminates his employment for good reason, which is defined to include, among other reasons, resigning for any reason during the 12-month period after a change in control, Mr. Cohen will be eligible to receive severance equal to 12 months of his then current base salary.

Danny L. Dearen

We entered into an employment agreement with Mr. Dearen in May 2014 under which Mr. Dearen will serve as our Chief Operating and Financial Officer. In August 2018, Mr. Dearen was appointed our President and

will no longer serve as our Chief Operating Officer. Mr. Dearen will retain his title and responsibilities as our Chief Financial Officer. The agreement provides that Mr. Dearen's term will run from May 22, 2014 to July 1, 2019, sets forth his initial base salary of $300,000, which will be reviewed on an annual basis, and his eligibility to receive such medical coverage and other benefits available to senior executives. Mr. Dearen's employment may terminate earlier than July 1, 2019, upon Mr. Dearen's death or disability (meaning he is unable to perform his duties for more than 26 substantially consecutive weeks in any 12-month period). We may also terminate Mr. Dearen for cause (which includes acts that would constitute misappropriation, embezzlement or fraud, materially and adversely impact our business or reputation, conviction of, or entering into a plea of no contest of, a felony, and any breach of the agreement that remains uncured after providing notice to Mr. Dearen of the breach) at any time, and we may terminate Mr. Dearen without cause upon 30 days' prior written notice. The agreement covers stock options granted to Mr. Dearen to purchase 79,395 shares of common stock, which will accelerate and vest in full in the event there is a change in control before or within 90 days following termination of Mr. Dearen's service. These options have been exercised by Mr. Dearen in accordance with their terms. Mr. Dearen's employment agreement also includes proprietary inventions and confidential information provisions.

Further, under the employment agreement, if Mr. Dearen's employment terminates prior to March 1, 2019 by reason of death or disability, Mr. Dearen or his estate will be eligible to receive severance equal to 12 months of base salary, conditioned upon his or his agent's execution of a waiver and release agreement. If we terminate Mr. Dearen's employment prior to July 1, 2019 without cause, including after a change in control, or if he terminates his employment for good reason, which is defined to include, among other reasons, resigning for any reason during the 12-month period after a change in control, Mr. Dearen will be eligible to receive severance equal to 12 months of his then current base salary.

Karen Noblett, M.D.

We entered into an employment agreement with Dr. Noblett in October 2017 under which Dr. Noblett will serve as our Chief Medical Officer. The agreement provides that Dr. Noblett's term as our Chief Medical Officer will run from October 2, 2017 to October 2, 2021, sets forth her initial base salary of $350,000, and her eligibility to receive such medical coverage and other benefits available to senior executives. We have also agreed to sponsor Dr. Noblett's attendance of University of California, Irvine for the purposes of gaining an executive M.B.A, which is acknowledged to cost approximately $110,000. Dr. Noblett's employment may terminate earlier than July 1, 2019, upon Dr. Noblett's death or disability (meaning she is unable to perform her duties for more than 26 substantially consecutive weeks in any 12-month period). We may also terminate Dr. Noblett for cause (which includes acts that would constitute misappropriation, embezzlement or fraud, materially and adversely impact our business or reputation, conviction of, or entering into a plea of no contest of, a felony, and any breach of the agreement that remains uncured after providing notice to Dr. Noblett of the breach) at any time, and we may terminate Dr. Noblett without cause upon 30 days' prior written notice. The agreement covers stock options granted to Dr. Noblett to purchase 14,963 shares of common stock, which will accelerate and vest in full in the event there is a change in control before or within 90 days following termination of Dr. Noblett's service. These options have been exercised by Dr. Noblett in accordance with their terms. Dr. Noblett's employment agreement also includes proprietary inventions and confidential information provisions.

Further, under the employment agreement, if Dr. Noblett's employment terminates prior to March 1, 2019 by reason of death or disability, Dr. Noblett or her estate will be eligible to receive severance equal to six months of base salary, conditioned upon her or her agent's execution of a waiver and release agreement. If we terminate Dr. Noblett's employment without cause, including after a change in control, or if she terminates her employment for good reason, which is defined to include, among other reasons, resigning for any reason during the 12-month period after a change in control, Dr. Noblett will be eligible to receive severance equal to six months of her then current base salary.

401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The 401(k) plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which was $18,000 for calendar year 2017. Participants who are 50 years or older can also make "catch-up" contributions, which in calendar year 2017 was up to an additional $6,000 above the statutory limit. We currently make matching contributions under our 401(k) plan of 100% on the first 3% of the participant's compensation and 50% between 3% and 5% of compensation, subject to IRS limits. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

Nonqualified Deferred Compensation

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Director Compensation

We did not pay any compensation to any non-employee member of our board of directors or to Mr. Cohen for service on our board of directors during the year ended December 31, 2017. All compensation paid to Mr. Cohen is for services rendered as our Chief Executive Officer. We do not currently have an established plan or policy with regard to compensation of members of our board of directors. We intend to establish a plan or policy with regard to compensation of members of our board of directors after the completion of this offering.

Limitations on Liability and Indemnification Matters

Our certificate of incorporation will contain provisions that limit the personal liability of our directors for monetary damages to the fullest extent permitted by the DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for any of the following: (i) breach of the director's duty of loyalty to us or our stockholders; (ii) an act or omission not in good faith or that involves intentional misconduct or a knowing violation of law; (iii) unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or (iv) a transaction from which the director derives an improper personal benefit.

Our bylaws will provide that we must indemnify our directors and other officers, and may indemnify our employees or agents, to the maximum extent permitted by Section 145 of the DGCL.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to the indemnification that will be provided for in our certificate of incorporation and bylaws, as they will be in effect upon completion of this offering. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these provisions in our certificate of incorporation, bylaws and indemnification agreements will be necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions that will be set forth in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of

their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. To the extent we pay the costs of settlement or a damage award against any director or officer pursuant to these indemnification provisions, our stockholders' investment may be harmed.

Except as otherwise disclosed under the heading "Legal Proceedings" in the "Business" section of this prospectus, there is at present no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2015 and each currently proposed transaction to which we have been or are a party, in which the amount involved in the transaction exceeded or will exceed $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than compensation arrangements for our directors and executive officers, which are described in "Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

AMF License Agreement

In October 2013, we entered into the License Agreement with AMF, pursuant to which we license the AMF IP to develop and commercialize the AMF Licensed Products. For a more detailed description of the License Agreement, see "Business—AMF License Agreement." As of June 30, 2018, AMF holds 888,000 shares of our common stock, 125,000 shares of our Series A preferred stock, and 771,161 shares of our Series B-1 preferred stock. John Petrovich, a member of our board of directors, is the President, Chief Executive Officer, Senior Vice President of Business Development, and General Counsel of AMF.

Preferred Stock Financings

In March 2014, we completed the sale of an aggregate of 1,030,000 shares of our Series A preferred stock at a purchase price of $20.00 per share for an aggregate purchase price of approximately $20.6 million. Of the 1,030,000 shares, 719,500 shares were issued as shares of our Series A preferred stock, and 310,500 shares were issued as shares in Axonics Europe S.A.S, or Axonics Europe, on an as-exchanged basis at the applicable exchange rate, or the Series A exchange shares. Immediately prior to the completion of this offering, the Series A exchange shares will automatically be exchanged for 310,500 shares of our Series A preferred stock pursuant to the Share Exchange Agreement, which is defined below.

In addition, in connection with the amendment of the License Agreement in February 2014, in order to, among other things, include the field of the treatment of urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, within the scope of the licenses granted therein, an option under the License Agreement that required us to pay $1,000,000, we instead issued and sold to AMF 50,000 shares of our Series A preferred stock.

All outstanding shares of our Series A preferred stock, including all Series A exchange shares once automatically exchanged, will automatically convert into 2,386,105 shares of our common stock upon the completion of this offering.

Series B-1 and Series B-2 Preferred Stock Financing

In January 2016, we completed the sale of an aggregate of 2,529,862 shares of our Series B-1 preferred stock at a purchase price of $7.20 per share and an aggregate of 2,537,231 shares of our Series B-2 preferred stock at a purchase price of $8.00 per share, for an aggregate purchase price of approximately $20.08 million in cash proceeds plus the conversion of the principal and accrued interest on certain promissory notes of $18.22 million.

Of the 2,529,862 shares of Series B-1 preferred stock, 1,925,302 shares were issued as shares of our Series B-1 preferred stock, and 604,560 were issued as shares in Axonics Europe, on an as-exchanged basis at the applicable exchange rate, or the Series B-1 exchange shares. Immediately prior to the completion of this offering, the Series B-1 exchange shares will automatically be exchanged for 604,560 shares of our Series B-1 preferred stock pursuant to the Share Exchange Agreement.

Of the 2,537,231 shares of Series B-2 preferred stock, 2,213,794 were issued as shares of our Series B-2 preferred stock, and 323,437 were issued as shares in Axonics Europe, on an as-exchanged basis at the applicable exchange rate, or the Series B-2 exchange shares. Immediately prior to the completion of this offering, the Series B-2 exchange shares will automatically be exchanged for 323,437 shares of our Series B-2 preferred stock pursuant to the Share Exchange Agreement.

The shares referenced above were issued in two closings, with the initial closing of 2,529,862 shares of our Series B-1 preferred stock, including the Series B-1 exchange shares, and 2,334,106 shares of Series B-2 preferred stock, including the Series B-2 exchange shares, closing in December 2015, and the second closing of 203,125 shares of our Series B-2 preferred stock, including Series B-2 exchange shares, closing in January 2016.

All outstanding shares of our Series B-1 preferred stock, including all Series B-1 exchange shares once automatically exchanged, will automatically convert into 3,035,837 shares of our common stock upon the completion of this offering. All outstanding shares of our Series B-2 preferred stock, including all Series B-2 exchange shares once automatically exchanged, will automatically convert into 3,044,680 shares of our common stock upon the completion of this offering.

The following table summarizes purchases of shares of our Series B-1 preferred stock, including the Series B-1 exchange shares, and our Series B-2 preferred stock, including the Series B-2 exchange shares, by holders of more than 5% of our capital stock, a member of our board of directors and an entity affiliated with a member of our board of directors.

	Initial Closing			Second Closing				
Participants	Shares of Series B-1 Preferred Stock	Shares of Series B-2 Preferred Stock	Aggregate Purchase Price(2)	Shares of Series B-2 Preferred Stock	Aggregate Purchase Price	Total Shares of Series B-1 Purchased	Total Shares of Series B-2 Purchased	Aggregate Purchase Price(2)
Greater than 5% Stockholders(1)								
BioDiscovery 4 FCPR(3)(4)	671,733	359,375	$ 7,711,477.60	—	$ —	671,733	359,375	$ 7,711,477.60
NeoMed Innovation V, L.P.(5)	379,675	203,125	$ 4,358,660.00	—	$ —	379,675	203,125	$ 4,358,660.00
Noble Prestige Holdings Limited	379,415	—	$ 2,731,788.00	203,125	$ 1,625,000.00	379,415	203,125	$ 4,356,788.00
AMF(6)	771,161	—	$ 5,552,359.20	—	$ —	771,161	—	$ 5,552,359.20
Advent Life Sciences Fund II LLP(7)(8)	—	1,062,499	$ 8,499,992.00	—	—	—	1,062,499	$ 8,499,992.00
Director								
Raymond W. Cohen	7,300	—	$ 52,560.00	—	$ —	7,300	—	$ 52,560.00

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the caption “Principal Stockholders.”

(2) A portion of the consideration paid for the shares of Series B-1 and B-2 preferred stock issued in the initial closing was funded through the conversion of the aggregate principal amount and accrued interest of certain convertible promissory notes.

(3) Assumes full exercise of all exchange rights of the Series B-1 exchange shares and the Series B-2 exchange shares under the Share Exchange Agreement.

(4) Raphaël Wisniewski, who is a member of our board of directors, is a Partner of Andera Partners, which is the Manager of BioDiscovery 4 FCPR.

(5) Erik Amble, Ph.D., who is a member of our board of directors, is the Chair of NeoMed Innovation V, L.P.

(6) John Petrovich, who is a member of our board of directors, is the President, Chief Executive Officer, Senior Vice President of Business Development, and General Counsel of AMF.

(7) Includes 36,518 shares of Series B-2 preferred stock purchased in the second closing by Advent Life Sciences LLP.

(8) Shahzad Malik, M.B. BChir, who is a member of our board of directors, is a General Partner of Advent Life Sciences LLP, which is the General Partner of Advent Life Sciences Fund II LLP.

A portion of the consideration paid for the shares of Series B-1 and B-2 preferred stock issued in the initial closing was funded through the conversion of the aggregate principal amount and accrued interest of certain convertible promissory notes.

Our Chief Executive Officer and member of our board of directors, Raymond W. Cohen, participated in the offering. As a result of this offering, Advent Life Sciences Fund II LLP, of which our director Shahzad Malik, M.B. BChir, may be deemed to hold voting or investment control, became a beneficial owner of more than 5% of our outstanding shares of our common stock.

Series C Preferred Stock Financing

In March 2018, we completed the sale of an aggregate of 6,122,222 shares of our Series C preferred stock at a purchase price of $9.00 per share for an aggregate purchase price of approximately $55.0 million. Of the 6,122,222 shares, 4,131,546 of these shares were issued as shares of our Series C preferred stock, and 1,900,676 were issued as shares in Axonics Europe, on an as-exchanged basis at the applicable exchange rate, or the Series C exchange shares. Immediately prior to the completion of this offering, the Series C exchange shares will automatically be exchanged for 1,900,676 shares of our Series C preferred stock pursuant to the Share Exchange Agreement.

The shares referenced above were issued in three tranches, with the first tranche of 1,606,255 shares, including the Series C exchange shares, closing in April 2017, the second tranche of 2,282,634 shares, including the Series C exchange shares, closing in June 2017, and the third tranche of 2,233,333 shares, including the Series C exchange shares, closing in March 2018.

All outstanding shares of our Series C preferred stock, including all Series C exchange shares once automatically exchanged, will automatically convert into 7,346,675 shares of our common stock upon the completion of this offering. The following table summarizes purchases of shares of our Series C preferred stock, including Series C exchange shares, by holders of more than 5% of our capital stock and an entity affiliated with a member of our board of directors.

	Initial Closing		Second Closing		Third Closing			
Participants	Shares of Series C Preferred Stock	Aggregate Purchase Price	Shares of Series C Preferred Stock	Aggregate Purchase Price	Shares of Series C Preferred Stock	Aggregate Purchase Price	Total Shares Purchased	Aggregate Purchase Price
Greater than 5% Stockholders(1)								
BioDiscovery 4 FCPR(2)(3)	545,197	$4,906,773	—	$ —	—	$ —	545,197	$ 4,906,773
NeoMed Innovation V, L.P.(4)	308,155	$2,773,395	—	$ —	—	$ —	308,155	$ 2,773,395
Noble Prestige Holdings Limited	111,111	$ 999,999	—	$ —	—	$ —	111,111	$ 999,999
Advent Life Sciences Fund II LLP(5)(6)	349,457	$3,145,113	—	$ —	—	$ —	349,457	$ 3,145,113
Coöperatieve Gilde Healthcare IV U.A.(2)(7)	—	$ —	1,666,666	$14,999,994	222,222	$ 1,999,998	1,888,888	$16,999,992
Longitude Venture Partners III, L.P.(8)	—	$ —	—	$ —	2,000,000	$18,000,000	2,000,000	$18,000,000

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the caption “Principal Stockholders.”

(2) Assumes full exercise of all exchange rights of the Series C exchange shares under the Share Exchange Agreement.

(3) Raphaël Wisniewski, who is a member of our board of directors, is a Partner of Andera Partners, which is the Manager of BioDiscovery 4 FCPR.

(4) Erik Amble, Ph.D., who is a member of our board of directors, is the Chair of NeoMed Innovation V, L.P.

(5) Includes 12,010 shares of Series C preferred stock purchased in the initial closing by Advent Life Sciences LLP.

(6) Shahzad Malik, M.B. BChir, who is a member of our board of directors, is a General Partner of Advent Life Sciences LLP, which is the General Partner of Advent Life Sciences Fund II LLP.

(7) Geoff Pardo, who is a member of our board of directors, is a Partner of Gilde Healthcare Partners, an entity affiliated with Coöperatieve Gilde Healthcare IV U.A.

(8) Juliet Tammenoms Bakker, who is a member of our board of directors, is a Managing Member of Longitude Capital Partners III, LLC, which is the General Partner of Longitude Venture Partners III, L.P.

As a result of this offering, Coöperatieve Gilde Healthcare IV, of which our director Geoff Pardo may be deemed to hold voting or investment control, and Longitude Venture Partners III, L.P., of which our director Juliet Tammenoms Bakker may be deemed to hold voting or investment control, each became beneficial owners of more than 5% of our outstanding shares of our common stock.

Investors' Rights Agreement

We are party to a Fourth Amended and Restated Investors' Rights Agreement, dated March 29, 2018, along with certain holders of our capital stock, which includes each investor in our preferred stock and certain of our directors (or, in some cases, entities affiliated therewith), or the Rights Agreement. The Rights Agreement grants certain rights to the holders, including certain registration rights with respect to the registrable securities held by them. See "Description of Capital Stock—Registration Rights" for additional information.

The Rights Agreement imposes certain affirmative obligations on us, including our obligation to, among others, (i) grant each holder of 5% of our capital stock a right of first offer with respect to future sales of our equity, excluding the shares to be offered and sold in this offering, (ii) invite a representative of each of Longitude Venture Partners III, L.P. and Noble Prestige Holdings Limited to attend all meetings of our board of directors in a non-voting observer capacity, and (iii) grant certain information and inspection rights to holders of 5% or more of our preferred stock. Each of these obligations will terminate in connection with the closing of this offering.

In addition, the Rights Agreement requires that at least two-thirds of the members of our board of directors approve certain transactions of our company, subject to limited exceptions, including, the incurrence or advance of any loan, the guarantee of any indebtedness, the incurrence of any indebtedness over $100,000, enter into related party transactions, change the compensation of any of the executive officers, change our strategy, amend or waive any provision of the License Agreement, commence or settle material litigation, sell or transfer material assets, undertake this offering, approve a budget, form a subsidiary, or authorize any class of security with rights on parity with or superior to our Series C preferred stock. We have entered into an amendment to the Rights Agreement setting forth that this heightened-board approval requirement will terminate in connection with the closing of this offering.

Voting Agreement

We are party to a Fifth Amended and Restated Voting Agreement, dated March 29, 2018, along with certain holders of our capital stock, which includes each investor in our preferred stock and certain of our

directors (or, in some cases, entities affiliated therewith), or the Voting Agreement. Pursuant to the Voting Agreement, each of BioDiscovery 4 FCPR, NeoMed Innovation V, L.P., AMF, Advent Life Sciences LLP, Coöperatieve Gilde Healthcare IV U.A., and Longitude Venture Partners III, L.P. has the right to designate one member to be elected to our board of directors. See "Management—Board Composition and Election of Directors." The Voting Agreement will terminate by its terms in connection with the closing of this offering and none of our stockholders will have any continuing rights regarding the election or designation of members of our board of directors following this offering.

Right of First Refusal and Co-Sale Agreement

We are party to a Second Amended and Restated Right of First Refusal and Co-Sale Agreement, dated April 28, 2017, along with certain holders of our capital stock, which includes each investor in our preferred stock and certain of our directors (or, in some cases, entities affiliated therewith), or the Co-Sale Agreement. Pursuant to the Co-Sale Agreement, we have a right of first refusal in respect of certain sales of securities by certain holders of our common stock, including Raymond W. Cohen, our Chief Executive Officer and a member of our board of directors, Danny L. Dearen, our President and Chief Financial Officer, and AMF, a holder of 5% or more of our outstanding capital stock. To the extent we do not exercise such right in full, the holders of our preferred stock are granted certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement will terminate in connection with the closing of this offering.

Share Exchange Agreement

We are party to a Fourth Amended and Restated Share Exchange Agreement, dated June 30, 2017, with BioDiscovery 4 FCPR and Coöperatieve Gilde Healthcare IV U.A., or the Share Exchange Agreement. Each of BioDiscovery 4 FCPR and Coöperatieve Gilde Healthcare IV U.A. have invested in our preferred stock. We and BioDiscovery 4 FCPR have established a French corporation, Axonics Europe, S.A.S., or Axonics Europe, to accommodate BioDiscovery 4 FCPR's requirement that a certain amount of the proceeds of its investment go directly to fund a subsidiary based in France. These proceeds were generally subsequently distributed to us.

Accordingly, the investment by BioDiscovery 4 FCPR and a portion of the aggregate investment by Coöperatieve Gilde Healthcare IV U.A. in our company, has been divided with ten percent being allocated to our company and ninety percent to Axonics Europe. As a result of the accommodation, we, BioDiscovery 4 FCPR and Coöperatieve Gilde Healthcare IV U.A. are holders of shares in Axonics Europe, or the French Shares, with BioDiscovery 4 FCPR and Coöperatieve Gilde Healthcare IV U.A. holding a majority of the French Shares.

Pursuant to the Share Exchange Agreement, each of BioDiscovery 4 FCPR and Coöperatieve Gilde Healthcare IV U.A. have the option to contribute and exchange their respective French Shares in exchange for the applicable series of our preferred stock at the applicable exchange ratio. This option will automatically be deemed to be exercised in full immediately prior to the closing of this offering. As a result, we will hold all outstanding French Shares immediately prior to the closing of this offering.

Loans to Executive Officers and Directors; Debt Forgiveness

We have agreed to pay for the early exercise of stock option awards of certain of our executive officers and directors under the 2014 Plan in exchange for their respective issuance of a secured full recourse promissory note, or the promissory note, for each exercise, and their respective entry into a stock pledge agreement, or pledge agreement, pledging such shares as collateral under each respective promissory note. Each of our executive officers and directors entered into substantially similar promissory notes and pledge agreements. Each promissory note bore interest at a rate of 4.5% per annum.

The following table demonstrates the loans made to our executive officers and directors based on each early option exercise and the respective balance of each promissory note as of October 4, 2018, which represents

the largest aggregate amount of principal outstanding during such time each respective promissory note was outstanding:

Executive Officers and Directors	Date of Loan	Principal Amount	Options Exercised	Exercise Price	Balance as of October 4, 2018
Raymond W. Cohen	4/21/2015	$ 115,052.28	119,020	$ 0.97	$ 132,953.15
	1/15/2016	$ 335,918.70	344,532	$ 0.98	$ 377,043.43
	5/23/2017	$ 91,132.82	69,215	$ 1.32	$ 96,739.36
	7/5/2017	$ 54,541.60	41,424	$ 1.32	$ 57,607.88
	8/25/2017	$ 106,761.70	75,362	$ 1.42	$ 112,092.47
Danny L. Dearen	11/30/2015	$ 76,747.92	79,395	$ 0.97	$ 86,579.01
Karen Noblett, M.D.	8/15/2017	$ 56,270.00	39,720	$ 1.42	$ 59,149.02
Prabodh Mathur	6/24/2015	$ 52,461.00	54,270	$ 0.97	$ 60,209.42
	1/15/2016	$ 109,000.71	111,796	$ 0.98	$ 122,345.08
	5/26/2017	$ 30,787.88	23,384	$ 1.32	$ 32,670.58
	8/15/2017	$ 17,661.24	13,414	$ 1.32	$ 18,564.87
	8/28/2017	$ 34,571.20	24,404	$ 1.42	$ 36,284.61
Guangqiang (Jay) Jiang, Ph.D.	6/18/2015	$ 45,974.28	47,560	$ 0.97	$ 52,798.63
	1/15/2016	$ 80,443.35	82,506	$ 0.98	$ 90,291.60
	7/22/2017	$ 17,661.24	13,414	$ 1.32	$ 18,617.12
	7/22/2017	$ 30,787.88	23,384	$ 1.32	$ 32,454.22
John Woock, Ph.D.	11/5/2015	$ 14,500.00	15,000	$ 0.97	$ 16,402.08
	2/9/2016	$ 66,331.98	68,033	$ 0.98	$ 74,248.20
	5/28/2017	$ 18,471.78	14,030	$ 1.32	$ 19,596.79
Michael V. Williamson	11/24/2015	$ 52,461.00	54,270	$ 0.97	$ 59,219.85
	2/15/2016	$ 109,000.71	111,796	$ 0.98	$ 121,928.49
Rinda Sama	7/14/2015	$ 34,974.00	36,180	$ 0.97	$ 40,053.37
	1/28/2016	$ 72,667.53	74,531	$ 0.98	$ 81,447.36
	5/25/2017	$ 59,112.54	44,896	$ 1.32	$ 62,734.60
	8/24/2017	$ 33,467.56	25,419	$ 1.32	$ 35,142.77
	8/26/2017	$ 65,507.80	46,241	$ 1.42	$ 68,770.63
Total					**$ 1,965,944.59**

We have entered into debt forgiveness and cancellation of note agreements with certain of our executive officers and directors, including each of our named executive officers, to terminate each of their respective promissory notes and to forgive all respective obligations for payment thereof in connection with this offering. Pursuant to such agreements, as the forgiveness of such loan obligations gives rise to income that is subject to tax withholding, certain of the above executive officers have respectively agreed to surrender to us an aggregate of 38,338 shares of our common stock as compensation for our tax withholding obligations, and a certain other executive officer has agreed to pay in cash our tax withholding obligation with respect to such officer.

Reserved Share Program

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to some of our directors, officers, employees, dealers, business associates and related persons. See “Underwriting—Reserved Shares.”

Participation in This Offering

Certain of our existing stockholders that are affiliated with certain of our directors have indicated an interest in purchasing an aggregate of up to approximately $45.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements

or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

Indemnification Agreements

We have entered into separate indemnification agreements with our directors and executive officers. The indemnification agreements require and our bylaws will require us to indemnify our directors to the fullest extent permitted by Delaware law. For more information regarding these agreements, see "Executive Compensation—Limitations on Liability and Indemnification Matters."

Policies and Procedures for Transactions with Related Persons

Prior to the completion of this offering, we plan to adopt a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration, ratification and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions) in which we and any "related person" are participants involving an amount that exceeds $120,000. Transactions involving compensation for services provided to us as directors or executive officers are not considered related-person transactions under this policy. A related person is any executive officer, director or a holder of more than 5% of any class of our equity, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee for review, consideration and approval. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions or other sources of comparable products or services are available. To identify related-person transactions in advance, we will rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval. Our audit committee will approve only those related-person transactions that are in the best interests of our company, as our audit committee determines in good faith.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock by:

- each of our named executive officers;
- each of our directors and director nominee;
- all of our executive officers and directors as a group; and
- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock.

The ownership information under the column entitled "Common Stock Beneficially Owned Prior to this Offering" is based on 18,638,600 shares of common stock outstanding as of June 30, 2018, after giving effect to the automatic exchange of the exchanged preferred stock immediately prior to the completion of this offering and the automatic conversion of all outstanding shares of our preferred stock, including the exchanged preferred stock, into shares of our common stock, which will occur upon completion of this offering. The ownership information under the column "Common Stock Beneficially Owned After this Offering" gives effect to the automatic conversion of all outstanding shares of our preferred stock as described above and our issuance of 6,667,000 shares of our common stock in this offering.

Information with respect to beneficial ownership has been furnished by each director, director nominee, officer or beneficial owner of more than five percent of our outstanding shares of common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days of June 30, 2018. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Certain of our existing stockholders that are affiliated with certain of our directors have indicated an interest in purchasing an aggregate of up to approximately $45.0 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering. The following table does not reflect any such potential purchases by these stockholders. If any shares are purchased by these affiliated entities, the number of shares of common stock beneficially owned after this offering and the percentage of common stock beneficially owned after this offering would increase from that set forth in the table below.

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.

Name and address of beneficial owner	Common Stock Beneficially Owned Prior to this Offering		Common Stock Beneficially Owned After this Offering	
	Number of Shares	%	Number of Shares	%
Named Executive Officers, Directors, and Director Nominee				
Raymond W. Cohen(1)	745,313	3.99%	745,313	2.94%
Danny L. Dearen(2)	281,501	1.50%	281,501	1.11%
Karen Noblett, M.D.(3)	58,286	*	58,286	*
Raphaël Wisniewski(4)	2,690,795	14.44%	2,690,795	10.63%
Erik Amble, Ph.D.(5)	1,520,884	8.16%	1,520,884	6.01%
Shahzad Malik, M.B. BChir(6)	1,694,349	9.09%	1,694,349	6.70%
John Petrovich(7)	2,102,970	11.28%	2,102,970	8.31%
Geoff Pardo(8)	2,266,666	12.16%	2,266,666	8.96%
Juliet Tammenoms Bakker(9)	2,400,000	12.88%	2,400,000	9.48%
Robert E. McNamara	—	*	—	*
All executive officers, directors, and director nominee as a group (16 persons)(10)	14,765,770	79.22%	14,765,770	58.35%
Greater than 5% Holders				
BioDiscovery 4 FCPR(11)	2,690,795	14.44%	2,690,795	10.63%
Longitude Venture Partners III, L.P.(12)	2,400,000	12.88%	2,400,000	9.48%
Coöperatieve Gilde Healthcare IV U.A.(13)	2,266,666	12.16%	2,266,666	8.96%
Alfred E. Mann Foundation for Scientific Research(14)	2,102,970	11.28%	2,102,970	8.31%
Advent Life Sciences Fund II LP(15)	1,694,349	9.09%	1,694,349	6.70%
NeoMed Innovation V L.P.(16).	1,520,884	8.16%	1,520,884	6.01%
Noble Prestige Holdings Limited(17)	1,284,120	6.89%	1,284,120	5.07%

* Less than 1%.

(1) Consists of (i) 694,553 shares of common stock held by Mr. Cohen, (ii) 42,000 shares of common stock underlying stock options exercisable within 60 days of June 30, 2018, 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.

(2) Consists of (i) 139,395 shares of common stock held by Mr. Dearen, and (ii) 142,106 shares of common stock underlying stock options exercisable within 60 days of June 30, 2018.

(3) Consists of (i) 39,720 shares of common stock held by Dr. Noblett, and (ii) 18,566 shares of common stock underlying stock options exercisable within 60 days of June 30, 2018.

(4) Consists of 2,690,795 shares held by BioDiscovery 4 FCPR. Andera Partners is the manager of BioDiscovery 4 FCPR and has voting and dispositive power over the shares held by BioDiscovery 4 FCPR. Mr. 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. As described under “Management—Board Composition and Election of Directors”, BioDiscovery 4 FCPR exercised a contractual right under the Voting Agreement by designating Mr. Wisniewski for nomination to our board of directors. The mailing address of BioDiscovery 4 FCPR is 347 Rue Saint St Honoré, 75001 Paris Cedex 08 France.

(5) Consists of 1,520,884 shares held by NeoMed Innovation V, L.P. 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. Mr. 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. As described under "Management—Board Composition and Election of Directors", NeoMed Innovation V, L.P. exercised a contractual right under the Voting Agreement by designating Mr. Amble for nomination to our board of directors. The mailing address of NeoMed Innovation V, L.P. is 13 Castle Street, St. Helier, Y9 JE4 5UT.

(6) 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. Malik, who is a member of our board of directors, 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. As described under "Management—Board Composition and Election of Directors", Advent Life Sciences LLP exercised a contractual right under the Voting Agreement by designating Dr. Malik for nomination to our board of directors. 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.

(7) Consists of 2,102,970 shares of common stock held by AMF. Mr. Petrovich, who is a member of our board of directors, is the President, Chief Executive Officer, Senior Vice President of Business Development, and General Counsel of AMF, and may be deemed to have voting and dispositive power over the shares held by AMF. Mr. Petrovich disclaims beneficial ownership of such shares. As described under "Management—Board Composition and Election of Directors", AMF exercised a contractual right under the Voting Agreement by designating Mr. Petrovich for nomination to our board of directors. The mailing address of AMF is 25134 Rye Canyon Loop, Santa Clarita, California 91355.

(8) Consists of 2,266,666 shares of common stock held by Coöperatieve Gilde Healthcare IV U.A. Mr. Pardo who is a member of our board of directors, is a partner of Coöperatieve Gilde Healthcare IV U.A., and may be deemed to have voting and dispositive power over the shares held by Coöperatieve Gilde Healthcare IV U.A. As described under "Management—Board Composition and Election of Directors", Coöperatieve Gilde Healthcare IV U.A. exercised a contractual right under the Voting Agreement by designating Mr. Pardo for nomination to our board of directors. The mailing address of Coöperatieve Gilde Healthcare IV U.A. is 222 Third Street, Suite 1321, Cambridge, Massachusetts 02142, c/o Gilde Healthcare Partners.

(9) Consists of 2,400,000 shares of common stock held by Longitude Venture Partners III, L.P. 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. Ms. 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. As described under "Management—Board Composition and Election of Directors", Longitude Venture Partners III, L.P. exercised a contractual right under the Voting Agreement by designating Ms. Tammenoms Bakker for nomination to our board of directors. The mailing address of Longitude Venture Partners III, L.P. is 2740 Sand Hill Road, 2nd Floor, Menlo Park, California 94025.

(10) Includes 284,524 shares of common stock underlying stock options exercisable within 60 days of June 30, 2018.

(11) See footnote (4) above.

(12) See footnote (9) above.

(13) See footnote (8) above.

(14) See footnote (7) above.

(15) See footnote (6) above.

(16) See footnote (5) above.

(17) Consists of 1,284,120 shares of common stock held by Noble Prestige Holdings Limited. LC Fund V, L.P. is the controlling stockholder of Noble Prestige Holdings Limited. Junfeng Wang is the Managing Director of LC Fund V, L.P. and may be deemed to have voting and dispositive power over the shares held by Noble Prestige Holdings Limited. The mailing address of Noble Prestige Holdings Limited is 10/F, Tower A, Raycom Info Tech Park No. 2 Kexueyuan Nanlu, Zhongguancun Haidaian District, Beijing 100190, P.R.

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, as they will be in effect in connection with the completion of this offering, 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 will be filed as exhibits to the registration statement of which this prospectus forms a part.

General

Upon the completion of this offering, our authorized capital stock will consist 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, 2018, and after giving effect to the automatic conversion of all of our outstanding preferred stock into common stock, there were outstanding 18,638,600 shares of our common stock held of record by 89 stockholders, 1,425,316 shares of our common stock issuable upon the exercise of outstanding stock options, and 40,001 shares of our common stock issuable upon the exercise of outstanding warrants.

Immediately after the completion of this offering, 25,305,600 shares of common stock will be outstanding, assuming the underwriters' option to purchase additional shares is not exercised, and no shares of preferred stock will be outstanding.

Common Stock

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

Voting

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

Dividends

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

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

Liquidation Rights

Upon our voluntary or involuntary liquidation, dissolution or winding up, after satisfaction of all our liabilities and the payment of any liquidation preference of any outstanding preferred stock, the holders of shares

of common stock will be entitled to share in all of our assets legally remaining for distribution after payment of all debt and other liabilities, subject to preferences that may be applicable to the holders of outstanding shares of preferred stock.

Redemption Rights

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

Preemptive Rights and Conversion Rights

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

Preferred Stock

Immediately prior to the closing of this offering, all outstanding shares of our preferred stock will convert into 15,813,297 shares of common stock. See Note 5 to our consolidated financial statements included elsewhere in this prospectus for a description of our currently outstanding preferred stock. Upon the completion of this offering, we will have no shares of our preferred stock outstanding, but our board of directors will be 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.

Options

As of June 30, 2018, options to purchase 1,425,316 shares of common stock were outstanding under the 2014 Plan, of which 496,995 were vested and 1,047,821 were exercisable as of such date. The difference in the amount of vested and exercisable options as of June 30, 2018 represents the rights of certain of our management to exercise their outstanding stock option awards early.

Warrants

In February 2018, we issued warrants to purchase an aggregate of 33,334 shares of our Series C preferred stock at an exercise price of $9.00 per share, of which warrants to purchase 33,334 shares of our Series C preferred stock remain outstanding as of June 30, 2018. In connection with this offering, these warrants will become exercisable for an aggregate of 40,001 shares of our common stock at an exercise price of $7.50 per share. These warrants may be exercised at any time and from time to time, in whole or in part. Unless earlier exercised, these warrants will expire in February 2028. In connection with our request of the full $5.0 million from Tranche B and the full $5.0 million from Tranche C in October 2018, each warrant will become exercisable for 33,333 shares of our Series C preferred stock.

Registration Rights

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, provided that we will not be required to effect such registration statement prior to the earlier of (i) March 29, 2021 and (ii) six months after the closing of this offering. 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

Following the closing of this offering, 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, including the right to exclude all such stockholder shares from this offering.

Expiration of Registration Rights

The registration rights under the Rights Agreement will expire upon the earlier of (i) the fifth anniversary of the closing of this offering and (ii) with respect to each holder following the closing of this 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 will initially have eight members. Our certificate of incorporation will provide 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 will authorize only our board of directors to fill vacant directorships.

No Cumulative Voting. Our certificate of incorporation will provide 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 will 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 will 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 will 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 will 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 will provide 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 will provide 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.

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 will, to the maximum extent permitted from time to time by Delaware law, renounce 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 will provide 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 will 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 Market Listing

We have applied to list our common stock on the Nasdaq Global 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.

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares outstanding as of June 30, 2018, upon completion of this offering, we will have outstanding an aggregate 25,305,600 shares of common stock (or 26,305,650 shares if the underwriters exercise in full their option to purchase additional shares of our common stock). This includes shares of common stock that we are selling in this offering, which shares may be resold in the public market immediately following this offering, and assumes (i) the automatic exchange of the exchanged preferred stock immediately prior to the completion of this offering, (ii) the automatic conversion of all outstanding shares of our preferred stock, including the exchanged preferred stock, into 15,813,297 shares of our common stock upon completion of this offering, and (iii) no exercise of outstanding stock options or warrants prior to completion of this offering.

The remaining 18,638,600 shares of common stock that were not offered and sold in this offering, and 1,425,316 shares subject to outstanding stock options will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act. All of these restricted securities will be subject to the 180-day lock-up period described below. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which are summarized below, or any other exemption and, if subject to lock-up agreements, may only be sold after the expiration of the 180-day lock-up period.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the completion of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 253,056 shares immediately after this offering; or
- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

Rule 701

Under Rule 701, shares of our common stock acquired upon the exercise of currently outstanding stock options or pursuant to other rights granted under the 2014 Plan may be resold by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and

- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

As of June 30, 2018, options to purchase 1,425,316 shares of common stock were outstanding under the 2014 Plan, of which 496,995 were vested and 1,047,821 were exercisable as of such date. The difference in the amount of vested and exercisable options as of June 30, 2018 represents the rights of certain of our management to exercise their outstanding stock option awards early. Of the total number of shares of our common stock issuable under these options, substantially all are subject to contractual lock-up agreements with us or the underwriters described below and will become eligible for sale at the expiration of those agreements unless held by an affiliate of ours.

Lock-Up Agreements

We, along with our directors, executive officers, and substantially all of our other existing equityholders have agreed that for a period of 180 days after the date of this prospectus, subject to certain exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC. See “Underwriting” for a more complete description of the lock-up agreements that we, our directors, executive officers, and substantially all of our other existing equityholders have entered into in connection with this offering.

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under the 2014 Plan and 2018 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

Registration Rights

Upon the closing of this offering, the holders of 16,701,297 shares of our common stock, including shares of our common stock issuable upon the conversion of all outstanding shares of our preferred stock, including the exchange shares, immediately prior to the closing of this offering, or their transferees will, subject to any lock-up agreements they have entered into, be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

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

As described in the section entitled "Dividend Policy," 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 and foreign accounts, 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, and the gross proceeds of, a disposition of 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, and the gross proceeds of, a disposition of 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.

The withholding provisions described in the preceding paragraph will generally apply to payments of dividends and will begin to apply to payments of gross proceeds from a sale or other disposition of our common stock on or after January 1, 2019.

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

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC 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 and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
Morgan Stanley & Co. LLC	
Wells Fargo Securities, LLC	
SunTrust Robinson Humphrey, Inc.	
Total	6,667,000

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 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 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 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.

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

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

The expenses of the offering, not including the underwriting discount, are estimated at $2.3 million 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 $50,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,000,050 additional 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.

Reserved Shares

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to certain of our directors, officers, employees, business associates and related persons through a reserved share program. If these persons purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus. We have agreed to reimburse the underwriters for certain fees and expenses in connection with this reserved shares program, including the fees and disbursements of counsel to the underwriters, up to an amount not to exceed $15,000.

No Sales of Similar Securities

We, our directors, executive officers, and substantially all of our other existing equityholders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC. 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.

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC, 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 180 days after the date of this prospectus. Notwithstanding any other provisions of the lock-up agreement, if Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC, 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 Market Listing

We expect the shares to be approved for listing on the Nasdaq Global Market, subject to notice of issuance, under the symbol “AXNX.”

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

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 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, no offer of ordinary shares which are the subject of the offering has been, or will be made to the public in that Member State, other than under the following exemptions under the Prospectus Directive:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of ordinary shares referred to in (a) to (c) above shall result in a requirement for the Company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Directive, or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person located in a Member State to whom any offer of ordinary shares is made or who receives any communication in respect of an offer of ordinary shares, or who initially acquires any ordinary shares will be deemed to have represented, warranted, acknowledged and agreed to and with each representative and the Company that (1) it is a "qualified investor" within the meaning of the law in that Member State implementing Article 2(1)(e) of the Prospectus Directive; and (2) in the case of any ordinary shares acquired by it as a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, the ordinary shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives has been given to the offer or resale; or where ordinary shares have been acquired by it on behalf of persons in any Member State other than qualified investors, the offer of those ordinary shares to it is not treated under the Prospectus Directive as having been made to such persons.

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

This prospectus has been prepared on the basis that any offer of shares in any Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly, any person making or intending to make an offer in that Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the representatives have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the representatives to publish a prospectus for such offer.

For the purposes of this provision, the expression an "offer of ordinary shares to the public" in relation to any ordinary 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 the ordinary shares to be offered so as to enable an investor to decide to purchase or subscribe the ordinary shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (as amended) and includes any relevant implementing measure in each Member State.

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 Directive) (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 the 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 the 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, the Company 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, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the 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 relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus 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 nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus 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 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 the 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 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 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 has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), 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) 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

(b) 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 (as defined in Section 239(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:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

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 (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 shares of common stock being offered by this prospectus will be passed upon for us by K&L Gates LLP, Irvine, California. Certain legal matters will be passed upon for the underwriters by Shearman & Sterling LLP, New York, New York.

EXPERTS

The consolidated financial statements as of and for the years ended December 31, 2017 and 2016 included in this prospectus and in the registration statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On August 29, 2018, we dismissed Peterson Sullivan LLP, or Peterson Sullivan, as our independent registered public accounting firm. This dismissal has been ratified by the audit committee of our board of directors.

Peterson Sullivan audited our consolidated financial statements for the years ended December 31, 2017 and 2016. The audit report issued by Peterson Sullivan on June 15, 2018, did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope, or accounting principles. Peterson Sullivan did not provide an audit opinion on our consolidated financial statements for any period subsequent to the year ended December 31, 2017.

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

We provided Peterson Sullivan with a copy of the foregoing disclosures and requested Peterson Sullivan to furnish us with a letter addressed to the SEC stating whether or not Peterson Sullivan agrees with the above disclosures. A copy of Peterson Sullivan’s letter is filed as Exhibit 16.1 to the registration statement of which this prospectus is a part.

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

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does 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 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. Upon completion of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. You may read and copy this information at the Public Reference Room of the SEC, 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is http://www.sec.gov. We also maintain a website at www.axonicsmodulation.com, at which, following the completion of this offering, you may access our SEC filings free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus. You may also request a copy of these filings, at no cost, by writing us at 26 Technology Drive, Irvine, California, 92618, Attention: Senior Vice President and General Counsel, or telephoning us at (949) 396-6322.

Axonics Modulation Technologies, Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Axonics Modulation Technologies, Inc. (the "Company") and subsidiaries as of December 31, 2017 and 2016, the related consolidated statements of comprehensive loss, mezzanine equity, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2017 and 2016, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Restatement to Correct 2017 and 2016 Misstatements

As discussed in Note 10 to the consolidated financial statements, the 2017 and 2016 consolidated financial statements have been restated to correct for misstatements.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ BDO USA, LLP

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

Costa Mesa, California

October 5, 2018, except for Note 12, as to which the date is October 22, 2018

Axonics Modulation Technologies, Inc.

Consolidated Balance Sheets

ASSETS	December 31, 2017 (restated)	December 31, 2016 (restated)	June 30, 2018 (unaudited, restated)
Current Assets			
Cash and cash equivalents	$ 24,397,548	$ 8,208,663	$ 24,729,223
Short-term investments	—	—	15,152,247
Accounts receivable	—	—	13,641
Inventory	1,541,325	—	1,913,244
Prepaid expenses and other current assets	979,668	520,181	1,621,363
Total current assets	26,918,541	8,728,844	43,429,718
Property and equipment, net	1,530,389	1,167,315	1,458,946
Intangible asset, net	540,687	655,515	483,272
Other assets	422,057	304,327	427,744
Total assets	$ 29,411,674	$ 10,856,001	$ 45,799,680
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT			
Current Liabilities			
Accounts payable	$ 1,615,722	$ 630,306	$ 2,087,404
Accrued liabilities	789,296	854,688	2,899,055
Total current liabilities	2,405,018	1,484,994	4,986,459
Lease liability, net of current portion	134,986	301,512	53,087
Debt, net of unamortized debt issuance costs	—	—	8,984,902
Total liabilities	2,540,004	1,786,506	14,024,448
Mezzanine Equity			
Convertible Preferred Stock			
Series A Convertible Preferred Stock, par value $0.0001, 1,030,000 shares authorized, 719,500 shares issued and outstanding at December 31, 2017 and 2016 and at June 30, 2018 (unaudited, restated); aggregate liquidation preference of $15,829,000 at December 31, 2017 and June 30, 2018 (unaudited, restated)	14,020,451	14,020,451	14,020,451
Series B-1 Convertible Preferred Stock, par value $0.0001, 2,529,862 shares authorized, 1,925,302 shares issued and outstanding at December 31, 2017 and 2016 and at June 30, 2018 (unaudited, restated); aggregate liquidation preference of $15,248,392 at December 31, 2017 and June 30, 2018 (unaudited, restated)	13,757,424	13,757,424	13,757,424
Series B-2 Convertible Preferred Stock, par value $0.0001, 2,537,231 shares authorized, 2,213,794 shares issued and outstanding at December 31, 2017 and 2016 and at June 30, 2018 (unaudited, restated); aggregate liquidation preference of $19,481,387 at December 31, 2017 and June 30, 2018 (unaudited, restated)	17,572,351	17,572,351	17,572,351
Series C Convertible Preferred Stock, par value $0.0001, 3,888,889 shares authorized at December 31, 2017 and 2016, 6,188,888 shares authorized at June 30, 2018 (unaudited, restated); 1,898,213, 0, and 4,131,546 shares issued and outstanding at December 31, 2017, December 31, 2016, and at June 30, 2018 (unaudited, restated), respectively; aggregate liquidation preference of $17,083,917 at December 31, 2017 and $37,183,914 at June 30, 2018 (unaudited, restated)	16,875,554	—	36,776,198
Noncontrolling interest in Axonics Europe, S.A.S.	31,066,420	13,150,330	31,066,420
Stockholders' Deficit			
Common Stock, par value $0.0001, 15,000,000 shares authorized at December 31, 2017 and 2016; 17,500,000 authorized at June 30, 2018 (unaudited); 2,776,583, 2,329,612 and 2,825,303 shares issued and outstanding at December 31, 2017, December 31 2016, and June 30, 2018 (unaudited), respectively	278	233	283
Additional paid-in capital	2,900,419	1,842,755	3,229,561
Stock subscription receivable	(1,752,700)	(1,178,404)	(1,823,670)
Accumulated deficit	(67,165,950)	(49,105,092)	(82,418,282)
Accumulated other comprehensive loss	(402,577)	(990,553)	(405,504)
Total stockholders' deficit	(66,420,530)	(49,431,061)	(81,417,612)
Total liabilities, mezzanine equity and stockholders' deficit	$ 29,411,674	$ 10,856,001	$ 45,799,680

See accompanying notes to consolidated financial statements.

Axonics Modulation Technologies, Inc.

Consolidated Statements of Comprehensive Loss

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2016	2018 (unaudited)	2017 (unaudited)
Net revenue	$ 128,118	$ —	$ 12,239	$ —
Cost of goods sold	117,944	—	5,354	—
Gross profit	10,174	—	6,885	—
Operating Expenses				
Research and development	12,332,046	12,510,280	10,721,150	5,826,504
General and administrative	4,822,541	4,457,275	3,070,531	2,417,413
Sales and marketing	1,029,915	516,076	1,359,642	398,636
Total operating expenses	18,184,502	17,483,631	15,151,323	8,642,553
Loss from operations	(18,174,328)	(17,483,631)	(15,144,438)	(8,642,553)
Other Income (Expense)				
Interest income	200,579	84,020	275,732	41,511
Interest expense	—	—	(377,965)	—
Loss on disposal of property and equipment	(65,397)	—	—	—
State income tax expense	(890)	(800)	(800)	(800)
Other expense	(20,822)	(291)	(4,861)	(5,203)
Net loss	**(18,060,858)**	**(17,400,702)**	**(15,252,332)**	**(8,607,045)**
Foreign currency translation adjustment	587,976	(291)	(2,927)	68,867
Comprehensive loss	**$ (17,472,882)**	**$ (17,400,993)**	**$ (15,255,259)**	**$ (8,538,178)**
Net loss per share, basic and diluted (see Note 1)	**$ (7.04)**	**$ (7.52)**	**$ (5.43)**	**$ (3.60)**
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	**2,564,964**	**2,313,526**	**2,811,183**	**2,389,066**
Pro forma net loss per share, basic and diluted (see Note 1) (unaudited)	**$ (0.98)**		**$ (0.82)**	
Pro forma weighted-average shares used to compute basic and diluted net loss per share (see Note 1) (unaudited)	**18,378,261**		**18,624,480**	

See accompanying notes to consolidated financial statements.

Axonics Modulation Technologies, Inc.

Consolidated Statements of Mezzanine Equity (restated)

	Series A Convertible Preferred Stock		Series B-1 Convertible Preferred Stock		Series B-2 Convertible Preferred Stock		Series C Convertible Preferred Stock		Noncontrolling Interest	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount		
Balance at December 31, 2015	719,500	$14,020,451	1,925,302	$13,757,424	2,010,669	$15,947,351	—	$ —	$ 13,150,330	$ 56,875,556
Issuance of Series B-2 Preferred Stock at $8.00 per share for cash	—	—	—	—	203,125	1,625,000	—	—	—	1,625,000
Balance at December 31, 2016	719,500	14,020,451	1,925,302	13,757,424	2,213,794	17,572,351	—	—	13,150,330	58,500,556
Issuance of Series C Preferred Stock at $9.00 per share for cash, net of issuance costs of $208,357	—	—	—	—	—	—	1,898,213	16,875,554	17,916,090	34,791,644
Balance at December 31, 2017	719,500	14,020,451	1,925,302	13,757,424	2,213,794	17,572,351	1,898,213	16,875,554	31,066,420	93,292,200
Issuance of Series C Preferred Stock at $9.00 per share for cash, net of issuance costs of $199,353 (unaudited)	—	—	—	—	—	—	2,233,333	19,900,644	—	19,900,644
Balance at June 30, 2018 (unaudited)	719,500	$14,020,451	1,925,302	$13,757,424	2,213,794	$17,572,351	4,131,546	$36,776,198	$ 31,066,420	$113,192,844

See accompanying notes to consolidated financial statements.

Axonics Modulation Technologies, Inc.

Consolidated Statements of Stockholders' Deficit (restated)

	Common Stock		Additional Paid-In Capital	Stock Subscriptions Receivable	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount					
Balance at December 31, 2015	1,523,218	$ 152	$ 735,126	$ (392,170)	$ (31,704,390)	$ (990,262)	$ (32,351,544)
Issuance of Common Stock for employee stock option exercises for promissory notes at $0.97 per share	806,394	81	786,153	(786,234)	—	—	—
Stock-based compensation	—	—	321,476	—	—	—	321,476
Foreign currency translation adjustment	—	—	—	—	—	(291)	(291)
Net loss	—	—	—	—	(17,400,702)	—	(17,400,702)
Balance at December 31, 2016	2,329,612	233	1,842,755	(1,178,404)	(49,105,092)	(990,553)	(49,431,061)
Issuance of Common Stock for employee stock option exercises for promissory notes	424,788	43	574,253	(574,296)	—	—	—
Issuance of Common Stock for employee stock option exercises for cash	22,183	2	22,181	—	—	—	22,183
Stock-based compensation	—	—	461,230	—	—	—	461,230
Foreign currency translation adjustment	—	—	—	—	—	587,976	587,976
Net loss	—	—	—	—	(18,060,858)	—	(18,060,858)
Balance at December 31, 2017	2,776,583	278	2,900,419	(1,752,700)	(67,165,950)	(402,577)	(66,420,530)
Issuance of Common Stock for employee stock option exercises for promissory notes (unaudited)	48,720	5	70,965	(70,970)	—	—	—
Stock-based compensation (unaudited)	—	—	258,177	—	—	—	258,177
Foreign currency translation adjustment (unaudited)	—	—	—	—	—	(2,927)	(2,927)
Net loss (unaudited)	—	—	—	—	(15,252,332)	—	(15,252,332)
Balance at June 30, 2018 (unaudited)	2,825,303	$ 283	$ 3,229,561	$ (1,823,670)	$ (82,418,282)	$ (405,504)	$ (81,417,612)

See accompanying notes to consolidated financial statements.

Axonics Modulation Technologies, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,		Six Months Ended June 30,	
	2017	2016	2018 (unaudited)	2017 (unaudited)
Cash Flows from Operating Activities				
Net loss	$ (18,060,858)	$ (17,400,702)	$ (15,252,332)	$ (8,607,045)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	725,394	625,117	427,586	334,746
Loss on disposal of property and equipment	65,397	—	—	—
Stock-based compensation	461,230	321,476	258,177	195,946
Amortization of debt issuance costs	—	—	118,036	—
Changes in operating assets and liabilities				
Accounts receivable	—	—	(13,641)	—
Inventory	(1,541,325)	—	(371,919)	(591,169)
Prepaid expenses and other current assets	(459,487)	(131,039)	(641,695)	(378,288)
Other assets	(198,956)	(50,952)	(41,357)	(27,219)
Accounts payable	985,416	(1,016,893)	471,682	453,458
Accrued liabilities	(52,374)	398,463	1,121,752	240,155
Deferred rent, noncurrent portion	(98,318)	(80,726)	—	(44,028)
Lease liability	—	—	(48,426)	—
Net cash used in operating activities	(18,173,881)	(17,335,256)	(13,972,137)	(8,423,444)
Cash Flows from Investing Activities				
Purchases of property and equipment	(1,039,037)	(292,115)	(298,729)	(249,987)
Purchase of short-term investments	—	—	(15,152,247)	—
Net cash used in investing activities	(1,039,037)	(292,115)	(15,450,976)	(249,987)
Cash Flows from Financing Activities				
Payment of debt issuance costs	—	—	(142,929)	—
Proceeds from debt	—	—	10,000,000	—
Proceeds from issuance of Preferred Stock and noncontrolling interest	35,000,001	1,625,000	20,099,997	20,000,007
Payment of Preferred Stock issuance costs	(208,357)	—	(199,353)	(86,641)
Proceeds from exercise of stock options	22,183	—	—	9,177
Net cash provided by financing activities	34,813,827	1,625,000	29,757,715	19,922,543
Effect of Exchange Rate Changes on Cash and Cash Equivalents	587,976	(291)	(2,927)	68,867
Net increase (decrease) in cash and cash equivalents	**16,188,885**	**(16,002,662)**	**331,675**	**11,317,979**
Cash and Cash Equivalents, beginning of year	8,208,663	24,211,325	24,397,548	8,208,663
Cash and Cash Equivalents, end of period	$ 24,397,548	$ 8,208,663	$ 24,729,223	$ 19,526,642
Supplemental Disclosure of Cash Flow Information				
Cash paid for interest	$ —	$ —	$ 204,583	$ —
Cash paid for income taxes	$ 890	$ 800	$ 800	$ 800
Noncash Investing and Financing Activities				
Common Stock issuance on stock option exercises for promissory notes	$ 574,296	$ 786,234	$ 70,970	$ 204,737
Warrants issued as debt issuance costs	$ —	$ —	$ 240,205	$ —
Accrued loan fees as debt issuance costs	$ —	$ —	$ 750,000	$ —

See accompanying notes to consolidated financial statements.

Axonics Modulation Technologies, Inc.

Notes to Consolidated Financial Statements

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

Nature of Operations

Axonics Modulation Technologies, Inc. (the "Company"), formerly American Restorative Medicine, Inc., was incorporated in the state of Delaware on March 2, 2012. The Company is a medical technology company focused on the design, development, and commercialization of innovative and minimally invasive sacral neuromodulation solutions. The Company has designed and developed the r-SNM System, which delivers mild electrical pulses to the targeted sacral nerve in order to restore normal communication to and from the brain to reduce the symptoms of overactive bladder ("OAB") and fecal incontinence ("FI"). The r-SNM System is protected by intellectual property based on Company-generated innovations and patents and other intellectual property licensed from the Alfred E. Mann Foundation for Scientific Research ("AMF"). The Company had no operations until October 1, 2013, when the license agreement between AMF and the Company (the "License Agreement") was entered into. The Company has obtained marketing approvals in Europe, Canada, and Australia for OAB, urinary retention, and FI, and expects to submit a pre-market approval ("PMA") application with the U.S. Food and Drug Administration ("FDA") for urinary urgency incontinence, a predominant OAB subtype, during the first quarter of 2019. The Company has derived minimal revenue from its operations, and its activities have consisted primarily of developing the r-SNM System, conducting its RELAX-OAB post-market clinical follow-up study in Europe, and its ARTISAN-SNM pivotal clinical study in the United States.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company, its wholly-owned subsidiary, Axonics Modulation Technologies U.K. Limited, as well as Axonics Europe, S.A.S., a variable interest entity, in which the Company exercises control and is determined to be the primary beneficiary. The interests held by the other investors in Axonics Europe can be converted at any time into a fixed number of shares of the Company's preferred stock. Due to this conversion right, the investors' interests are considered to be protected from any losses in Axonics Europe (see Note 5). Therefore, the Company is considered responsible to absorb the losses of Axonics Europe and as such, has a variable interest in Axonics Europe. Axonics Europe has no equity at risk and is therefore considered a variable interest entity since it is dependent on the Company to finance its activities. The investors in Axonics Europe have entered into an agreement with the Company acknowledging that their investment is not intended to give them voting control over Axonics Europe and they have agreed to vote as directed by the Company's board. Therefore, the Company is the primary beneficiary of Axonics Europe and consolidates this entity. Axonics Modulation Technologies U.K. Limited and Axonics Europe, S.A.S. did not have significant operations in 2017, 2016 or for the six months ended June 30, 2018 and 2017 (unaudited). Intercompany accounts and transactions have been eliminated in consolidation.

Basis of Presentation and Liquidity

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP").

The Company has incurred significant losses since inception, and as of December 31, 2017, had an accumulated deficit of $67,165,950. As of June 30, 2018 (unaudited), the Company had an accumulated deficit of $82,418,282, which includes a net loss of $15,252,332 for the six months ended June 30, 2018 (unaudited). The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding to commercialize the r-SNM System. The Company has relied on its ability to obtain financing, which to date has been through proceeds from the sale of convertible preferred stock and amounts borrowed under the

Loan Agreement (as defined below). Management expects operating losses and negative cash flows to continue in the near term as the Company incurs additional costs and expenses related to completing development, testing, and obtaining regulatory approval in the United States of the r-SNM System, which could lead to possible discontinuance of operations.

The Company's ability to meet its obligations in the ordinary course of business is dependent upon its ability to raise working capital through debt or additional equity financing, which the Company was able to do subsequent to December 31, 2017. See Note 11 for discussion of the additional debt and equity financings.

The Company believes that its current cash at December 31, 2017, including the amounts drawn under the Loan Agreement, will be sufficient to meet its forecasted requirements for operating liquidity, capital expenditure and debt repayments for at least one year from the date of issuance of these consolidated financial statements. However, there can be no assurances that it will be successful in obtaining financing in the future.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires the Company's management to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses, and related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and such differences may be material to the consolidated financial statements.

Revenue Recognition

Revenue recognized during the year ended December 31, 2017 and the six months ended June 30, 2018 (unaudited), relates entirely to the sale of product to two customers. The Company recognizes revenue when title and risk of loss pass to customers, which is typically when the customer takes possession of the product.

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

Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments purchased with an original maturity of three months or less. Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. At times, the cash and cash equivalent balances may exceed federally insured limits. The Company does not believe that this results in any significant credit risk.

Fair Value of Financial Instruments

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

- Level 1: Inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs are quoted prices for similar assets and liabilities in active markets or quoted prices for identical or similar instruments in markets that are not active and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
- Level 3: Inputs are unobservable inputs based on the Company's assumptions and valuation techniques used to measure assets and liabilities at fair value. The inputs require significant management judgment or estimation.

The Company's assessment of the significance of an input to the fair value measurement requires judgment, which may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels. The carrying amounts reported in the consolidated financial statements approximate the fair value for cash and cash equivalents, accounts receivable, accounts payables, and accrued expenses, due to their short-term nature. The carrying amount of the Company's term loan, which is described below, approximates fair value, considering the interest rates are based on the prime interest rate.

Investment Securities

The Company classifies its investment securities as available-for-sale. Those investments with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based upon quoted market prices at period end (Level 1 inputs in the fair value hierarchy) and consists primarily of commercial paper and U.S. government securities. Unrealized gains or losses, deemed temporary in nature, are reported as a separate component of comprehensive income (loss). There were no unrealized gains or losses during the six months ended June 30, 2018 (unaudited).

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

Foreign Currency Translation

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Costs and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' deficit in accumulated other comprehensive loss until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss). As of December 31, 2017 and 2016 and June 30, 2018 (unaudited), all foreign currency translation gains (losses) have been unrealized and included in accumulated other comprehensive loss. Accumulated other comprehensive loss consists entirely of losses from

translation of foreign subsidiaries at December 31, 2017 and 2016 and June 30, 2018 (unaudited). Foreign currency transaction gains and losses are included in results of operations and have not been significant for the periods presented.

Inventory

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

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

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

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

The Company analyzes inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its net realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of the r-SNM System is subject to strict quality control, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to the Company's inventory values. The Company also applies judgment related to the results of quality tests that are performed throughout the production process, as well as the understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre- and post-production processes, and the Company continually gathers information regarding product quality for periods after the manufacturing date. The r-SNM System currently has a maximum estimated shelf life range of 12 to 27 months and, based on sales forecasts, the Company expects to realize the carrying value of the product inventory. In the future, reduced demand, quality issues, or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

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

The r-SNM System inventory manufactured prior to international regulatory approval consisted of raw materials and work-in-process inventory, which was expensed as research and development costs as incurred and was combined with other research and development expenses. While management tracked the quantities of individual product lots, it did not track pre-regulatory approval manufacturing costs and, therefore, the manufacturing cost of the r-SNM System raw materials and work-in-process inventory produced prior to regulatory approval is not reasonably determinable. However, based on management's expectations for future manufacturing costs to produce the r-SNM System inventory, management estimates that approximately $450,000 of commercial r-SNM System inventory was expensed prior to regulatory approval.

The Company began capitalizing the r-SNM System manufacturing costs as inventory following both the receipt of regulatory approval from the European and Canadian regulatory bodies and the Company's intent

to commercialize, which occurred in 2017. As of December 31, 2017, the Company had $227,559, $2,986, and $1,310,780 of finished goods inventory, work-in-process inventory, and raw materials inventory, respectively, on hand. As of June 30, 2018, the Company had $599,705, $9,150, and $1,304,389 of finished goods inventory, work-in-process inventory, and raw materials inventory, respectively, on hand (unaudited).

The aggregate selling price of reduced-cost finished goods inventory on hand may be affected by a number of factors including, but not limited to, market demand, future pricing of the product, competition, and reimbursement by government and other payers. At this time, management of the Company cannot reasonably estimate the timing and rate of consumption of reduced-cost raw materials and work-in-progress inventory, or the timing of sales of finished goods manufactured with this inventory. The time period over which reduced-cost finished goods inventory is consumed will depend on a number of factors, including the amount of future r-SNM System sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date.

Property and Equipment

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

Intangible Asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The additional field-of-use was provided in exchange for 50,000 shares of Series A preferred stock, the fair value of which was $1,000,000 in 2013. The intangible asset was recorded at its fair value of $1,000,000 at the date contributed. Amortization of this asset is recorded over the shorter of the patent or legal life on a straight-line basis. The weighted-average amortization period is 8.71 years. The Company will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net cash flows that the assets are expected to generate. If said assets are considered to be impaired, the impairment that would be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets to date.

Leases

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

Effective January 1, 2018, the Company early adopted the comprehensive new lease standard. The most significant impact was the recognition of right-of-use (“ROU”) assets and lease liabilities for operating leases. Adoption of the standard required us to restate certain previously reported results, including the recognition of

additional ROU assets and lease liabilities for operating leases. The Company recorded an ROU asset of approximately $0.2 million, $0.1 million, and $0.1 million on its consolidated balance sheets at December 31, 2016, December 31, 2017, and June 30, 2018 (unaudited), respectively. The Company also recorded a lease liability of approximately $0.5 million, $0.3 million, and $0.2 million on its consolidated balance sheets at December 31, 2016, December 31, 2017, and June 30, 2018 (unaudited), respectively. The standard did not have an impact on the Company's consolidated statements of comprehensive loss. The Company determines if an arrangement is a lease at inception and includes operating leases on the Company's consolidated balance sheets. The operating lease ROU asset is included within the Company's other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company's consolidated balance sheets.

Operating lease ROU asset and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

As of December 31, 2017 and June 30, 2018, the remaining lease term for the Company's operating lease was 1.8 years and 1.3 years, respectively. The discount rate used to determine the present value of this operating leases's future payments was 6.75%.

Noncontrolling Interests

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

Research and Development

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

Income Taxes

The Company accounts for income taxes using the asset and liability method to compute the difference between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. The Company has deferred tax assets. The realization of these deferred tax assets is dependent upon the Company's ability to generate sufficient taxable income in future years. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. The Company evaluates the recoverability of the deferred tax assets annually.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The Company has determined that it has no uncertain tax positions.

Stock-Based Compensation

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

Preferred Stock

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

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

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

Net Loss per Share of Common Stock

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

For the years ended December 31, 2017 and 2016 and the six months ended June 30, 2018 and 2017, there were 8,059,999, 6,492,849, 10,685,599, and 7,245,703 potentially dilutive shares, respectively, that were not included in the computation of diluted weighted-average shares of common stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss.

Unaudited Pro Forma Net Loss per Share of Common Stock

The unaudited pro forma basic and diluted net loss per share reflects the conversion of all outstanding and issuable shares of convertible preferred stock into shares of common stock as if the conversion had occurred at the earlier of the beginning of the period or the date of issuance, if later. Convertible preferred stock outstanding and issuable includes shares of the Company and shares in Axonics Europe, S.A.S., which are exchangeable for the applicable series of convertible preferred stock pursuant to the Company's Fourth Amended and Restated Share Exchange Agreement, dated June 30, 2017, by and among the Company, BioDiscovery 4 FCPR, and Coöperative Gilde Healthcare IV U.A (the "Share Exchange Agreement").

Unaudited Interim Financial Information

The accompanying interim consolidated balance sheet as of June 30, 2018, the interim consolidated statements of comprehensive loss and cash flows for the six months ended June 30, 2018 and 2017, the interim consolidated statements of mezzanine equity and stockholders' deficit for the six months ended June 30, 2018, and the related footnote disclosures are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with GAAP and, in management's opinion, on a basis consistent with the audited consolidated financial statements and reflect all adjustments, which only include normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2018 and its results of operations and comprehensive loss and cash flows for the six months ended June 30, 2018 and 2017, and the consolidated statements of mezzanine equity and stockholders' deficit for the six months ended June 30, 2018.

The results for the six months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ended December 31, 2018 or for any other interim period.

Note 2. Property and Equipment

Property and equipment, net consists of the following at:

	December 31, 2017	December 31, 2016	June 30, 2018 (unaudited)
Research and development equipment	$ 783,254	$ 796,928	$ 821,275
Computer hardware and software	545,189	457,480	625,611
Tools and molds	876,717	393,502	1,040,433
Leasehold improvements	296,614	296,614	299,006
Furniture and fixtures	181,258	160,364	195,436
	2,683,032	2,104,888	2,981,761
Less: accumulated depreciation and amortization	(1,152,643)	(937,573)	(1,522,815)
	$ 1,530,389	$1,167,315	$ 1,458,946

Depreciation and amortization expense of property and equipment was $610,566, $510,289, $370,172, and $277,332 for the years ended December 31, 2017 and 2016, and the six months ended June 30, 2018 and 2017 (unaudited), respectively.

Note 3. Intangible Asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The intangible asset was recorded at its fair value of $1,000,000 at the date contributed in 2013, which is the gross carrying amount of the intangible asset at December 31, 2017, 2016, and June 30, 2018 (unaudited). Accumulated amortization of the intangible asset is $459,313, $344,485, and $516,728 at December 31, 2017, 2016, and June 30, 2018 (unaudited), respectively. The Company recorded expense for the amortization of intangible assets of $114,828 for both the years ended December 31, 2017 and 2016, and $57,414 for both the six months ended June 30, 2018 and 2017 (unaudited). The estimated future amortization expense as of December 31, 2017, is as follows:

2018	$114,828
2019	114,828
2020	114,828
2021	114,828
2022	81,375
	$540,687

Note 4. Commitments

Operating Leases

In August 2014, the Company entered into a five-year operating lease for approximately 12,215 square feet of office space beginning on November 1, 2014, and expiring on October 31, 2019. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term.

Rent expense (including the Company's proportionate share of taxes, insurance, and maintenance expenses) for the years ended December 31, 2017 and 2016 and the six months ended June 30, 2018 and 2017 (unaudited), was $204,831, $288,358, $175,855, and $98,244, respectively.

The future minimum lease payments of this operating lease as of December 31, 2017, are as follows:

2018	$212,546
2019	183,230
	$395,776

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

Unless earlier terminated, the term of the Lease (the "Initial Term") will expire on the final day of the calendar month following the seventh anniversary of the commencement date. The commencement date was set as August 2018. The Company did not control the leased premises before the commencement date. The aggregate base rent due over the Initial Term under the terms of the Lease is approximately $5.3 million (without giving effect to certain rent abatement terms). The Company will also be responsible for the payment of additional rent to cover certain costs, taxes, and insurance. Based on the estimated monthly additional rent for 2018 as set forth in the Lease, the Company estimates that the additional rent during the Initial Term will be approximately $3.8 million. The Company also expects to pay approximately $0.5 million for leasehold improvements, net of the tenant improvement allowance provided in the Lease of approximately $0.8 million.

The Company has a renewal option to extend the term of the Lease for a period of five years (the "Renewal Term") beyond the Initial Term. Under the terms of the Lease, the base rent payable with respect to each Renewal Term will be equal to the prevailing market rental rent as of the commencement of the applicable Renewal Term. In the event of a default of certain of the Company's obligations under the Lease, the Company's landlord would have the right to terminate the Lease. The Company is assessing the accounting impact of the Lease.

License Agreement

In October 2013, the Company entered into the License Agreement with AMF, pursuant to which AMF agreed to license to the Company certain patents and know-how (collectively, the "AMF IP") relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (collectively, the "AMF Licensed Products"). Pursuant to the License Agreement, AMF granted to the Company a royalty-bearing, sublicensable (by written, executed agreements only, subject to the terms of the License Agreement) license under the AMF IP to make,

have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of (i) chronic pain in humans through the application of electrical energy to the nervous system, (ii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve, a nerve that interfaces with parasympathetic control of the heart, lungs and digestive tract, and (iii) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system. Pursuant to the License Agreement, the Company is obligated to pay a 4% royalty of all net revenue derived from the AMF Licensed Products if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to the Company by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case, subject to certain adjustments. The initial term of the License Agreement is from October 1, 2013 to October 1, 2033, and will automatically continue until all patents are no longer in force. The Company generated net revenue of $128,118 and recorded related royalties of $4,972 during the year ended December 31, 2017. No revenue was generated and no payments were made during the year ended December 31, 2016 or during the six months ended June 30, 2017 (unaudited). Beginning in 2018, the Company is required to pay a minimum annual royalty under the License Agreement. The minimum amount will be $75,000 for 2018, with an increase in subsequent years of $25,000 (i.e., $100,000 for 2019) up to a maximum of $200,000 per year. The Company generated net revenue of $12,239 and recorded minimum royalties of $37,500 during the six months ended June 30, 2018 (unaudited).

Note 5. Stockholders' Equity

Preferred Stock

As of December 31, 2017, the Company is authorized to issue 9,985,982 shares of convertible preferred stock with a par value of $0.0001. The authorized shares of preferred stock are designated as Series A, Series B-1, Series B-2, and Series C preferred stock in the amount of 1,030,000, 2,529,862, 2,537,231, and 3,888,889 shares, respectively. The rights, preferences, and privileges of the Series A, Series B-1, Series B-2, and Series C preferred stock (collectively, the "Preferred Stock") are as follows:

Dividends

The holders of the outstanding shares of Preferred Stock are entitled to receive, when and if declared by the board of directors, a noncumulative dividend prior and in preference to any declaration or payment of any dividend of the common stock of the Company. As of June 30, 2018 (unaudited), no dividends have been declared since inception.

Conversion

Each share of Preferred Stock is convertible at any time, at the option of the holder, into that number of fully paid shares of common stock as determined by dividing the original issue price by the conversion price for the shares. The original issue price was $20.00, $7.20, $8.00, and $9.00 per share for Series A, B-1, B-2, and C, respectively. The conversion price is subject to adjustment in accordance with the provisions contained in the Company's Certificate of Incorporation. As of December 31, 2017, the conversion price for Series A, B-1, B-2, and C was $8.83, $6.00, $6.67, and $7.50 per share, respectively, based on the retroactive adjustment due to the Company's 1.2-for-1 forward stock split described in Note 12. As of June 30, 2018 (unaudited), the conversion price for Series A, B-1, B-2, and C was $8.63, $6.00, $6.67, and $7.50 per share, respectively, based on the retroactive adjustment due to the Company's 1.2-for-1 forward stock split described in Note 12.

Each share of Preferred Stock shall automatically converts into shares of common stock at the then-effective conversion price for such share immediately upon the earlier of (i) the Company's sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities

Act of 1933, as amended, in which the public offering price per share is not less than $12.00 (as adjusted for recapitalizations and the like) and the aggregate gross proceeds to the Company are not less than $50,000,000 or (ii) upon the election of the holders of at least two-thirds of the outstanding shares of Preferred Stock, voting together as a single class on an as-if converted to common stock basis. Each of the events described in (i) and (ii) is referred to as an "Automatic Conversion Event."

Liquidation

In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, the holders of Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of the common stock of the Company by reason of their ownership of such stock, an amount per share for each Preferred Stock share held by them equal to the sum of (i) 1.1 times the original issue price for the Preferred Stock for Series A and Series B holders and 1.0 times the original issue price for the Preferred Stock for Series C holders and (ii) all declared but unpaid dividends (if any) on such share. If upon the liquidation, dissolution, or winding up of the Company, the assets of the Company legally available for distribution to the holders of the preferred stock are insufficient to permit the payment to such holders of the full amounts, then the entire assets of the Company legally available for distribution shall be distributed ratably among the holders of Preferred Stock in proportion to the full amounts they would otherwise be entitled to receive. After the payment or setting aside for payment to the holders of Preferred Stock of the full amounts specified above, the entire remaining assets of the Company legally available for distribution shall be distributed with equal priority and pro rata among the holders of Preferred Stock and common stock then outstanding in proportion to the number of shares of common stock held by each, with each share of Preferred Stock being treated for this purpose as if it had been converted to common stock at the then-applicable conversion rate.

Voting

The holder of each share of Preferred Stock is entitled to the number of votes equal to the number of shares of common stock into which each share of Preferred Stock can be converted.

Stock Option Plan

In 2014, the Company established its 2014 Stock Option Plan (the "2014 Plan"), which provides for the granting of stock options to employees, directors, and consultants of the Company. Options granted under the 2014 Plan may be either incentive stock options ("ISOs") or nonstatutory stock options ("NSOs"), as determined by the administrator at the time of grant. The term of each option shall be stated in the option agreement; however, the term shall be no more than ten years from the date of the grant thereof. In the case of an ISO granted to an optionee who, at the time the option is granted, owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company, the term of the option shall be five years from the date of grant or such shorter term as may be provided in the option agreement. As of December 31, 2017 and June 30, 2018 (unaudited), a total of 2,652,903 and 3,178,593 shares have been reserved for issuance under the 2014 Plan, respectively. As of December 31, 2017 and June 30, 2018 (unaudited), there are 82,463 and 37,971 shares available for grant under the 2014 Plan, respectively.

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

	December 31, 2017	December 31, 2016	June 30, 2018 (unaudited)
Convertible preferred stock outstanding and issuable	13,079,920	8,264,962	15,813,297
Options outstanding under the 2014 Plan	903,857	476,451	1,425,316
Options remaining under the 2014 Plan for future issuance	82,463	20	37,971
	14,066,240	8,741,433	17,276,584

Preferred Stock outstanding and issuable includes shares of the Company and shares in Axonics Europe, S.A.S., which are exchangeable for the applicable series of Preferred Stock pursuant to the Share Exchange Agreement.

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

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

	Years ended December 31,		Six months ended June 30,	
	2017	2016	2018	2017
			(unaudited)	
General and administrative	$ 267,945	$ 193,977	$ 156,483	$ 120,821
Research and development	179,354	112,226	96,829	75,125
Sales and marketing	13,931	15,273	4,865	—
	$ 461,230	$ 321,476	$ 258,177	$ 195,946

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

	Years ended December 31,		Six months ended June 30,	
	2017	2016	2018	2017
			(unaudited)	
Expected term (in years)	5.00 - 6.50	6.06 - 6.27	5.00 - 6.96	5.00 - 6.50
Stock volatility	70.61% - 76.01%	70.73% - 70.85%	76.01% - 77.03%	70.61% - 76.01%
Risk-free interest rate	1.82% - 2.11%	1.36% - 1.78%	2.26% - 2.81%	1.83% - 2.03%
Dividend rate	0%	0%	0%	0%

The Company used the simplified method of determining the expected term of stock options. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments, whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The assumptions regarding the expected term of the options and the expected volatility of the stock price are subjective, and these assumptions have a significant effect on the estimated fair value amounts. The weighted-average grant date fair value of options granted was $0.88, $0.62, $1.10, and $0.83 for the years ended December 31, 2017 and 2016, and the six months ended June 30, 2018 and 2017 (unaudited), respectively.

As of December 31, 2017 and June 30, 2018 (unaudited) there was $888,584 and $1,253,350, respectively, of total unrecognized compensation cost related to non-vested stock options that is expected to be recognized over a weighted-average period of approximately 2.9 years.

The following table summarizes stock option activity under the 2014 Plan:

	Number of Options	Weighted-Average Exercise Price per Share
Outstanding at December 31, 2015	135,606	$ 0.97
Options granted	1,147,239	0.98
Options exercised	(806,394)	0.97
Outstanding at December 31, 2016	476,451	0.98
Options granted	896,828	1.36
Options exercised	(446,971)	1.33
Options forfeited	(22,451)	0.97
Outstanding at December 31, 2017	903,857	1.18
Options granted (unaudited)	570,179	1.35
Options exercised (unaudited)	(48,720)	1.46
Outstanding at June 30, 2018 (unaudited)	1,425,316	$ 1.35
Options exercisable at December 31, 2017	638,305	$ 1.18
Options exercisable at June 30, 2018 (unaudited)	1,047,821	$ 1.33

The weighted-average remaining contractual term of options outstanding and exercisable is 8.7 years, 8.0 years and 8.0 years, respectively, at December 31, 2017, 2016 and June 30, 2018 (unaudited). During the years ended December 31, 2017 and 2016 and six months ended June 30, 2018 and 2017 (unaudited), stock options covering 446,971, 806,394, 48,720 and 164,945 shares of common stock, respectively, with a total intrinsic value of $12,854, $0, $0, and $0 for 2017, 2016 and the six months ended June 30, 2018 and 2017 (unaudited), respectively, were exercised.

Stock Subscriptions Receivable

As of December 31, 2017, several members of management of the Company have exercised stock options covering 1,636,877 shares of common stock, in exchange for promissory notes with a principal balance of $1,752,700. As of June 30, 2018 (unaudited), there were additional exercises of stock options for promissory notes covering 48,720 shares of common stock. These promissory notes bear interest at a rate of 4.5% per annum and are due in full in 2020 to 2022. The promissory notes can become due earlier if the shares of common stock received from the option exercises are sold, the employee terminates employment with the Company, or pursuant to other provisions specified in the notes. The notes are secured by the shares of common stock received from the option exercises.

Preferred Stock Warrants (unaudited)

In February 2018, in connection with the Company's entry into the Loan Agreement (as defined below), the Company issued warrants to the Bank (as defined below) and Life Science Loans II, LLC, its counterparty. Each warrant entitles the holder thereof to purchase up to 33,333 shares of the Series C Preferred Stock at an exercise price of $9.00 per share. Initially, each warrant is exercisable for 16,667 shares of Series C Preferred Stock. If the Company draws on Tranche B (as defined below), an additional 8,333 shares will become exercisable under each warrant and if the Company draws on Tranche C (as defined below), an additional 8,333 shares will become exercisable under each warrant. Each warrant will expire on February 6, 2028. As of June 30, 2018 (unaudited), warrants to purchase 33,334 shares of the Company's Series C Preferred Stock were outstanding and are considered liabilities, the value of which is recorded in current liabilities and will be required to be adjusted to fair value each reporting period with the change reflected in the statements of comprehensive loss, if any. Additional warrants exercisable into a total of 33,332 Series C Preferred Stock shares remain

issuable as of June 30, 2018. The fair value of the warrants was estimated using the Black-Scholes Model with the following assumptions: expected life of 10 years, risk-free interest rate of 2.74% and stock volatility of 76.01%.

Note 6. Noncontrolling Interest

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

The Company presents noncontrolling interest as mezzanine equity on the consolidated balance sheets due to the Share Exchange Agreement that provides the holders of the equity in Axonics Europe S.A.S. (excluding the Company) the unilateral right to exchange its equity interest in Axonics Europe S.A.S. for Preferred Stock of the Company at any time. The Company's Preferred Stock is presented as mezzanine equity, and as such, the rights under the Share Exchange Agreement require the noncontrolling interest to be presented as mezzanine equity as well.

Comprehensive loss attributable to the noncontrolling interest in Axonics Europe S.A.S. are absorbed by the Company since the investors are protected from any losses in this entity due to the conversion right. Changes in amounts attributable to the redeemable noncontrolling interest are presented in the Company's consolidated statements of mezzanine equity.

Note 7. Income Taxes

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

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

	December 31,	
	2017	2016
Compensation accruals	$ 100,896	$ 129,406
Depreciation and amortization	(37,180)	(66,795)
Deferred rent	22,266	44,153
Net operating loss carryforwards	18,249,597	19,037,099
R&D tax credit carryforwards	1,425,200	1,065,409
Other	17,229	217
Total deferred tax assets	19,778,008	20,209,489
Less: valuation allowance	(19,778,008)	(20,209,489)
Total net deferred tax assets	$ —	$ —

On December 22, 2017, "H.R.1," known as the Tax Cuts and Jobs Act (the "Tax Act") was signed into law in the United States. Among other items, H.R.1 reduces the federal corporate tax rate to 21% from the existing maximum rate of 35%, effective January 1, 2018. As a result, the Company revalued its net deferred tax asset at the new lower tax rate at December 31, 2017. The change in the valuation allowance was a decrease of $431,481 and an increase of $6,944,236 for the years ended December 31, 2017 and 2016, respectively. At

December 31, 2017, the Company had federal and California net operating loss ("NOL") carryforwards of approximately $65.2 million. Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), use of the Company's NOL carryforwards may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a rolling three-year period. The Company has not performed an analysis of changes in ownership for purposes of these code sections. Ownership changes could impact the Company's ability to utilize NOL carryforwards remaining at an ownership change date. NOLs expire between 2033 and 2037. At December 31, 2017, the Company also had research and development tax credit carryforwards of approximately $1.9 million, which will expire in 2035 to 2037. Approximately $500,000 of these research and development tax credit carryforwards are included in prepaid expenses and other current assets on the balance sheet at December 31, 2017, as they are expected to be utilized in 2018 as a credit to offset payroll taxes. The remaining amount of research and development tax credit carryforwards are included in net deferred tax assets.

The Company used an annual effective tax rate approach to calculate income taxes for the six months ended June 30, 2018 and 2017 (unaudited). The annual effective tax rate of approximately 0% differs from the federal statutory tax rate due primarily to providing a full valuation allowance on deferred tax assets.

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

	Years Ended December 31,	
	2017	2016
Tax at statutory federal rate	34.0%	34.0%
State tax, net of federal benefit	5.8%	5.8%
Excess tax benefits related to stock-based compensation	(1.0)%	(0.7)%
Effect of Tax Cuts and Jobs Act of 2017	(37.5)%	0.0%
Change in valuation allowance	2.4%	(39.0)%
Other	(3.7)%	(0.1)%
Effective tax rate	0.0%	0.0%

Note 8. Employee Benefit Plan

The Company sponsors a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pre- or post-tax basis. Contributions to the plan by the Company may be made at the discretion of the board of directors. During the years ended December 31, 2017 and 2016, and the six months ended June 30, 2018 and 2017 (unaudited), the Company contributions to the plan amounted to $218,229, $181,186, $150,364, and $104,118, respectively.

Note 9. Related Party Transactions

The Company incurred $96,000, $96,000, $48,000, and $48,000 during the years ended December 31, 2017 and 2016, and the six months ended June 30, 2018 and 2017 (unaudited), respectively, to a scientific advisor who is also a non-management stockholder of the Company. Amounts payable to this advisor was $8,000 at December 31, 2017 and June 30, 2018 (unaudited). There were no amounts payable to this advisor at December 31, 2016.

The Company incurred $110,022, $266,491, $179,624, and $96,022 during the years ended December 31, 2017 and 2016, and the six months ended June 30, 2018 and 2017 (unaudited), respectively, for engineering and design services to a company that is owned by a non-management stockholder of the Company. There were no amounts payable to this company at December 31, 2017 or June 30, 2018 (unaudited). Amounts payable to this company was $12,359 at December 31, 2016.

The 2014 Plan allows for certain members of management to purchase vested options and unvested options (subject to repurchase rights) through a full recourse promissory note and stock pledge agreement. The promissory notes outstanding are recorded as Stock subscription receivable in the accompanying consolidated balance sheets. The notes were forgiven on October 4, 2018, refer to Note 11 for discussion of the note forgiveness. The aggregate principal amounts owed by certain members of management as of December 31, 2017 was $1,752,700.

Note 10. Restatement of Financial Statements

The Company determined that its consolidated financial statements for the years ended December 31, 2017 and 2016, and its interim consolidated financial statements for the six months ended June 30, 2018 included misstatements of the Company's stockholders' equity based on the terms and liquidation preferences on the Preferred Stock, resulting in the classification of the Preferred Stock in mezzanine equity instead of permanent equity. The change in classification of the Preferred Stock also resulted in the Company's warrants for Series C Preferred Stock to be treated as a liability instead of equity on the Company's consolidated balance sheets. The errors impact the Company's consolidated balance sheets, statements of mezzanine equity and stockholders' deficit in each period.

The Company previously presented Preferred Stock on the consolidated balance sheet assuming that the investors in Axonics Europe S.A.S., had converted all of their shares into the Company's Preferred Stock. Since the investors have not exercised their conversion option, they still hold noncontrolling interest in Axonics Europe S.A.S. The Company is correcting this error by disclosing only issued and outstanding shares as Preferred Stock and presenting noncontrolling interests in Axonics Europe S.A.S. as mezzanine equity.

The Company determined that its consolidated financial statements for the years ended December 31, 2017 and 2016, and its interim consolidated financial statements for the six months ended June 30, 2018 included misstatements of the Company's total assets and liabilities, based on the adoption of the comprehensive new lease standard. The Company applied the optional transition method, which allowed it to apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. As this optional transition method is not available for adoption at the time the Company applied it, the Company adopted the new lease standard using the modified retrospective approach, which required us to restate certain previously reported results, including the recognition of additional ROU assets and lease liabilities for operating leases. The errors impact the Company's consolidated balance sheets in each period.

The Company determined that its consolidated statements of comprehensive loss and cash flows for the years ended December 31, 2017 and 2016, and its unaudited interim consolidated statements of comprehensive loss and cash flows for the six months ended June 30, 2018 and 2017 were not impacted by the above misstatements.

The Company assessed the effect of the errors on prior periods' financial statements in accordance with SAB No. 99—Materiality and SAB No. 108—Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements and, based on quantitative and qualitative factors, determined that these errors were material to the consolidated financial statements for the years ended December 31, 2017 and 2016 and the six months ended June 30, 2018 (unaudited). As such, the Company has restated its consolidated financial statements for these periods.

The effect of the adjustments described above is presented in the following table.

December 31, 2016	As previously reported	Adjustments	Restated
Balance sheet data:			
Other assets	$ 107,947	$ 196,380	$ 304,327
Total assets	10,659,621	196,380	10,856,001
Accrued liabilities	773,462	81,226	854,688
Total current liabilities	1,403,768	81,226	1,484,994
Deferred rent, net of current portion	186,358	(186,358)	—
Lease liability, net of current portion	—	301,512	301,512
Total liabilities	1,590,126	196,380	1,786,506
Series A Convertible Preferred Stock (in mezzanine equity)	—	14,020,451	14,020,451
Series B-1 Convertible Preferred Stock (in mezzanine equity)	—	13,757,424	13,757,424
Series B-2 Convertible Preferred Stock (in mezzanine equity)	—	17,572,351	17,572,351
Series A Convertible Preferred Stock (in permanent equity)	103	(103)	—
Series B-1 Convertible Preferred Stock (in permanent equity)	253	(253)	—
Series B-2 Convertible Preferred Stock (in permanent equity)	254	(254)	—
Additional paid-in capital	60,342,701	(58,499,946)	1,842,755
Noncontrolling interest (in mezzanine equity)	—	13,150,330	13,150,330
Total stockholders' equity (deficit)	9,069,495	(58,500,556)	(49,431,061)
Total liabilities, mezzanine equity and stockholders' equity (deficit)	10,659,621	196,380	10,856,001

December 31, 2017	As previously reported	Adjustments	Restated
Balance sheet data:			
Other assets	$ 306,903	$ 115,154	$ 422,057
Total assets	29,296,520	115,154	29,411,674
Accrued liabilities	721,088	68,208	789,296
Total current liabilities	2,336,810	68,208	2,405,018
Deferred rent, net of current portion	88,040	(88,040)	—
Lease liability, net of current portion	—	134,986	134,986
Total liabilities	2,424,850	115,154	2,540,004
Series A Convertible Preferred Stock (in mezzanine equity)	—	14,020,451	14,020,451
Series B-1 Convertible Preferred Stock (in mezzanine equity)	—	13,757,424	13,757,424
Series B-2 Convertible Preferred Stock (in mezzanine equity)	—	17,572,351	17,572,351
Series C Convertible Preferred Stock (in mezzanine equity)	—	16,875,554	16,875,554
Series A Convertible Preferred Stock (in permanent equity)	103	(103)	—
Series B-1 Convertible Preferred Stock (in permanent equity)	253	(253)	—
Series B-2 Convertible Preferred Stock (in permanent equity)	254	(254)	—
Series C Convertible Preferred Stock (in permanent equity)	389	(389)	—
Additional paid-in capital	96,191,620	(93,291,201)	2,900,419
Noncontrolling interest (in mezzanine equity)	—	31,066,420	31,066,420
Total stockholders' equity (deficit)	26,871,670	(93,292,200)	(66,420,530)
Total liabilities, mezzanine equity and stockholders' equity (deficit)	29,296,520	115,154	29,411,674

June 30, 2018	As previously reported	Adjustments	Restated
Balance sheet data (unaudited):			
Accrued liabilities	2,658,850	240,205	2,899,055
Total current liabilities	4,746,254	240,205	4,986,459
Total liabilities	13,784,243	240,205	14,024,448
Series A Convertible Preferred Stock (in mezzanine equity)	—	14,020,451	14,020,451
Series B-1 Convertible Preferred Stock (in mezzanine equity)	—	13,757,424	13,757,424
Series B-2 Convertible Preferred Stock (in mezzanine equity)	—	17,572,351	17,572,351
Series C Convertible Preferred Stock (in mezzanine equity)	—	36,776,198	36,776,198
Series A Convertible Preferred Stock (in permanent equity)	103	(103)	—
Series B-1 Convertible Preferred Stock (in permanent equity)	253	(253)	—
Series B-2 Convertible Preferred Stock (in permanent equity)	254	(254)	—
Series C Convertible Preferred Stock (in permanent equity)	612	(612)	—
Additional paid-in capital	116,661,388	(113,431,827)	3,229,561
Noncontrolling interest (in mezzanine equity)	—	31,066,420	31,066,420
Total stockholders' equity (deficit)	32,015,437	(113,433,049)	(81,417,612)

Note 11. Subsequent Events

Term Loan

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

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

The Company may prepay amounts outstanding under the Term Loan in increments of $5.0 million at any time with 30 days prior written notice to the Bank. However, all prepayments of the Term Loan prior to maturity, whether voluntary or mandatory (acceleration or otherwise), are also subject to the payment of a prepayment fee equal to (i) for a prepayment made on or after the closing date through and including the first anniversary of the closing date, 3.00% of the principal amount of the Term Loan being prepaid, (ii) for a prepayment made after the date which is the first anniversary of the closing date through and including the

second anniversary of the closing date, 2.00% of the principal amount of the Term Loan being prepaid, and (iii) for a prepayment made after the date which is the second anniversary of the closing date and before the maturity date, 1.00% of the principal amount of the Term Loan being prepaid. Additionally, on the earliest to occur of (i) the maturity date of the Term Loan, (ii) the acceleration of the Term Loan, or (iii) the prepayment of the Term Loan, the Company will be required to make a final payment equal to the original principal amount of such Tranche multiplied by 7.50%. The Company is currently accruing the portion of the final payment calculated based on the amount outstanding under the Term Loan.

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

The outstanding balance of the Term Loan at June 30, 2018 (unaudited) is $10,000,000, which is presented net of unamortized debt issuance costs of $1,015,098. As the Company has met conditions to draw Tranche C and therefore not commence making monthly principal payments until January 2020, the outstanding balance of the Term Loan is classified in noncurrent liabilities at June 30, 2018 (unaudited).

Series C Preferred Stock Extension

In March 2018, the board of directors and certain stockholders of the Company approved amending the Company's certificate of incorporation to (i) increase the authorized shares of Preferred Stock from 9,985,862 shares to 12,285,981 shares, (ii) increase the authorized shares of common stock from 15,000,000 shares to 17,500,000 shares, and (iii) increase the designated Series C Preferred Stock from 3,888,889 shares to 6,188,888 shares. Additionally, the board of directors and certain stockholders of the Company also approved increasing the number of shares reserved for issuance under the 2014 Plan described in Note 5 from 2,652,903 shares to 3,178,593 shares.

In March 2018, the Company issued an additional 2,233,333 shares of Series C Preferred Stock to investors for gross cash proceeds of $20,099,997. The stock was issued on the same terms, rights, and privileges as the Series C Preferred Stock issued in 2017.

Forgiveness of Loans

On October 4, 2018, the Company entered into an agreement with each of Raymond W. Cohen, Danny L. Dearen, Karen Noblett, M.D., Prabodh Mathur, Guangqiang (Jay) Jiang, Ph.D., John Woock, Ph.D., Michael V. Williamson, and Rinda Sama to terminate each of their respective promissory notes and to forgive all respective obligations for payment thereof in connection with the Company's initial public offering. As a result, on October 4, 2018, the Company forgave loans to the officers referenced above in the aggregate amount of $1,965,944.59, which amount will be recorded as compensation expense.

Note 12. Stock Split and Charter Amendment

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

Through and including , 2018 (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

6,667,000 Shares

Axonics Modulation Technologies, Inc.

Common Stock

PROSPECTUS

BofA Merrill Lynch

Morgan Stanley

Wells Fargo Securities

SunTrust Robinson Humphrey

, 2018

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq Global Market listing fee.

	Amount to be paid
SEC registration fee	$ 14,868
FINRA filing fee	18,901
The Nasdaq Global Market listing fee	125,000
Printing and engraving expenses	275,000
Legal fees and expenses	1,300,000
Accounting fees and expenses	325,000
Transfer agent and registrar fees and expenses	5,000
Miscellaneous expenses	275,000
Total	$ 2,338,769

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law, or the DGCL, provides that a Delaware corporation may indemnify any persons who were, are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such corporation as an officer, director, employee or agent of another corporation or enterprise. Except in the case of an action by or in the right of the corporation (*i.e.*, a derivative action), the indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. With respect to an action by or in the right of the corporation, the indemnity may only include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if such person is adjudged to be liable, unless the Delaware Court of Chancery, or the court in which such action or suit was brought, determines that despite the adjudication of liability, such person is fairly and reasonably entitled to indemnity for such expenses. Where a present or former officer or director is successful on the merits or otherwise in the defense of any action, suit or proceeding referred to above, the corporation must indemnify him or her against the expenses (including attorneys' fees) by him or her in connection therewith.

Our amended and restated certificate of incorporation and amended and restated bylaws, each of which will become effective upon the completion of this offering, will provide for the indemnification of our directors and officers to the fullest extent permitted under the DGCL.

Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- willful or negligent violations of Delaware law governing the authorizations of dividends, stock repurchases, and redemptions, as provided in Section 174 of the DGCL; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation will include such a provision. Expenses incurred by any of our officers or directors in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of DGCL provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption, may be held liable for such actions. A director who was either absent when the unlawful actions were approved or dissented at the time may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of such action.

We have entered into separate indemnification agreements with our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by such director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or as a director, officer, employee or agent of any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

Except as otherwise disclosed under the heading "Legal Proceedings" in the "Business" section of this registration statement, there is at present no pending or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers and we intend to maintain such insurance coverage.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

The following sets forth information regarding all unregistered securities sold since January 1, 2015:

Sales of Preferred Stock and Issuance of Warrants

(1) In December 2015, we sold an aggregate of 2,529,862 shares of Series B-1 preferred stock to a total of eight accredited investors at a purchase price per share of $7.20 for an aggregate purchase price of $18,215,006.40.

(2) In December 2015 and January 2016, we sold an aggregate of 2,537,231 shares of Series B-2 preferred stock to a total of eleven accredited investors at a purchase price per share of $8.00 for an aggregate purchase price of $20,297,848.

(3) In April 2017, we sold an aggregate of 1,606,255 shares of Series C preferred stock to a total of eleven accredited investors at a purchase price per share of $9.00 for an aggregate purchase price of $14,456,295.

(4) In June 2017, we sold an aggregate of 2,282,634 shares of Series C preferred stock to a total of seven accredited investors at a purchase price per share of $9.00 for an aggregate purchase price of $20,543,706.

(5) In March 2018, we sold an aggregate of 2,233,333 shares of Series C preferred stock to a total of three accredited investors at a purchase price per share of $9.00 for an aggregate purchase price of $20,099,997.

(6) In February 2018, in connection with our loan and security agreement with Silicon Valley Bank, we issued warrants to Silicon Valley Bank to purchase 16,667 shares of Series C preferred stock at an exercise price of $9.00 per share, which may be exercised at any time and from time to time before expiration in February 2028. If we borrow an additional $5.0 million from with Silicon Valley Bank before December 31, 2018, the number of shares subject to this warrant will automatically increase by an additional 8,333 shares. In addition, if we borrow an additional $5.0 million from Silicon Valley Bank before March 31, 2019, the number of shares subject to this warrant will automatically increase by an additional 8,333 shares.

(7) In February 2018, in connection with our loan and security agreement with Silicon Valley Bank, we issued warrants to Life Science Loans II, LLC to purchase 16,667 shares of Series C preferred stock at an exercise price of $9.00 per share, which may be exercised at any time and from time to time before expiration in February 2028. If we borrow an additional $5.0 million from Silicon Valley Bank before December 31, 2018, the number of shares subject to this warrant will automatically increase by an additional 8,333 shares. In addition, if we borrow an additional $5.0 million from Silicon Valley Bank before March 31, 2019, the number of shares subject to this warrant will increase by an additional 8,333 shares.

Plan-Related Issuances

(8) Since March 1, 2014, we have granted to our directors, employees, consultants, and other service providers options to purchase 3,174,958 shares of our common stock with per share exercise prices ranging from $0.97 to $1.31 under the 2014 Plan.

(9) Since January 1, 2015, we have issued an aggregate of 1,720,591 shares of our common stock to employees, directors, consultants and other service providers upon their exercise of stock options, for aggregate consideration of $1,863,346.

None of the foregoing transactions involved any underwriters, underwriting discounts, or commissions, or any public offering. The offers, sales and issuances of securities listed above were deemed exempt from registration in reliance on Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder or

Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or transactions pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

See the Exhibit Index attached to this registration statement, which is incorporated by reference herein.

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

i. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

ii. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
1.1#	Form of Underwriting Agreement.
3.1#	Fourth Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2#	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of the Registrant, dated August 3, 2017.
3.3#	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of the Registrant, dated February 1, 2018.
3.4#	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of the Registrant, dated March 29, 2018.
3.5#	Certificate of Amendment of Fourth Amended and Restated Certification of Incorporation of the Registrant, dated October 18, 2018.
3.6#	Form of Amended and Restated Certificate of Incorporation, to be effective in connection with the completion of this offering.
3.7#	Bylaws of the Registrant, as currently in effect.
3.8#	Form of Amended and Restated Bylaws, to be effective in connection with the completion of this offering.
4.1#	Specimen certificate evidencing shares of common stock of the Registrant.
4.2#	Fourth Amended and Restated Investors' Rights Agreement, dated March 29, 2018, by and among the Registrant and the Investors party thereto.
4.3#	Amendment to Fourth Amended and Restated Investors' Rights Agreement, dated October 17, 2018, by and among the Registrant and the Investors party thereto.
4.4#	Warrant to Purchase Series C preferred stock, dated February 6, 2018, issued by the Registrant to Silicon Valley Bank.
4.5#	Warrant to Purchase Series C preferred stock, dated February 6, 2018, issued by the Registrant to Life Science Loans II, LLC.
5.1#	Opinion of K&L Gates LLP.
10.1†#	License Agreement, dated October 1, 2013, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.
10.2†#	First Amendment to License Agreement, dated February 19, 2014, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.
10.3†#	Second Amendment to License Agreement, dated February 25, 2014, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.
10.4#	Side Letter, dated October 1, 2013, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.
10.5+#	2014 Stock Incentive Plan, as amended.
10.6+#	Form of Option Award Agreement under 2014 Stock Incentive Plan.
10.7+#	Form of Restricted Stock Purchase Agreement under 2014 Stock Incentive Plan.
10.8+#	2018 Omnibus Incentive Plan.
10.9+#	Form of Option Award Agreement under 2018 Omnibus Incentive Plan.
10.10+#	Form of Restricted Shares Award Agreement under 2018 Omnibus Incentive Plan.
10.11+#	Form of RSU Award Agreement under 2018 Omnibus Incentive Plan.
10.12+#	Form of Indemnification Agreement by and between the Registrant and its directors and officers.

Exhibit Number	Exhibit Title
10.13#	Lease, dated November 30, 2017, by and between The Irvine Company LLC and the Registrant.
10.14#	First Amendment to Lease, dated April 12, 2018, by and between The Irvine Company LLC and the Registrant.
10.15#	Second Amendment to Lease, dated July 11, 2018, by and between The Irvine Company LLC and the Registrant.
10.16#	Loan and Security Agreement, dated February 6, 2018, by and between Silicon Valley Bank and the Registrant.
10.17+#	Executive Employment Agreement, dated May 22, 2014, by and between Raymond W. Cohen and the Registrant.
10.18+#	Executive Employment Agreement, dated May 22, 2014, by and between Danny L. Dearen and the Registrant.
10.19+#	Executive Employment Agreement, dated October 2, 2017, by and between Karen Noblett, M.D. and the Registrant.
10.20+#	Executive Employment Agreement, dated November 15, 2017, by and between Alfred Ford and the Registrant.
10.21+#	Executive Employment Agreement, dated May 22, 2014, by and between Guangqiang (Jay) Jiang, Ph.D. and the Registrant.
10.22+#	Executive Employment Agreement, dated May 22, 2014, by and between Prabodh Mathur and the Registrant.
10.23+#	Executive Employment Agreement, dated May 22, 2014, by and between Michael V. Williamson and the Registrant.
10.24+#	Executive Employment Agreement, dated July 24, 2018, by and between John Woock, Ph.D. and the Registrant.
10.25+#	Executive Employment Agreement, dated January 1, 2015, by and between Rinda Sama and the Registrant.
10.26+#	Form of Secured Full Recourse Promissory Note under 2014 Stock Incentive Plan.
10.27+#	Form of Stock Pledge Agreement under 2014 Stock Incentive Plan.
10.28+#	Form of Debt Forgiveness Agreement and Cancellation of Note (Tax Withholding—Shares).
10.29+#	Form of Debt Forgiveness Agreement and Cancellation of Note (Tax Withholding—Cash).
10.30#	Fourth Amended and Restated Share Exchange Agreement, dated June 30, 2017, by and among the Registrant, BioDiscovery 4 FCPR and Coöperatieve Gilde Healthcare IV U.A.
10.31#	Amendment to Loan and Security Agreement, dated October 22, 2018, by and between Silicon Valley Bank and the Registrant.
16.1#	Letter from Peterson Sullivan LLP to the Securities and Exchange Commission, dated October 5, 2018.
21.1#	List of subsidiaries.
23.1#	Consent of BDO USA, LLP, an independent registered public accounting firm.
23.2#	Consent of K&L Gates LLP (included in Exhibit 5.1).
24.1#	Power of Attorney (included on signature page).
99.1#	Consent of Director Nominee.

Previously filed.

+ Indicates management contract or compensatory plan.

† The Registrant has sought confidential treatment with respect to certain omitted portions of this exhibit.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Irvine, State of California, on the 25th day of October, 2018.

AXONICS MODULATION TECHNOLOGIES, INC.

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Raymond W. Cohen Raymond W. Cohen	Chief Executive Officer and Director (Principal Executive Officer)	October 25, 2018
/s/ Danny L. Dearen Danny L. Dearen	President and Chief Financial Officer (Principal Financial and Accounting Officer)	October 25, 2018
* Raphaël Wisniewski	Director	October 25, 2018
* Erik Amble, Ph.D.	Director	October 25, 2018
* Geoff Pardo	Director	October 25, 2018
* John Petrovich	Director	October 25, 2018
* Shahzad Malik, M.B. BChir	Director	October 25, 2018
* Juliet Tammenoms Bakker	Director	October 25, 2018

*By: /s/ Raymond W. Cohen
Raymond W. Cohen
Attorney-in-fact