UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

or

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

For the transition period from _____ to _____

Commission File Number: 001-38721

Axonics Modulation Technologies, Inc.

(Exact name of registrant as specified in its charter)

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

(949) 396-6322

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $1,135.8 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $35.11 per share for such date.

As of February 25, 2021, 41,523,375 shares of the registrant's common stock, par value $0.0001 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information that is required to be included in Part III of this Annual Report on Form 10-K is incorporated by reference to either a definitive proxy statement or an amendment to this Annual Report on Form 10-K to be filed by the registrant within 120 days of December 31, 2020. Only those portions of any such definitive proxy statement that are specifically incorporated by reference herein shall constitute a part of this Annual Report on Form 10-K.

TABLE OF CONTENTS

		Page
	Special Note Regarding Forward-Looking Statements	
	PART I	
Item 1.	Business	2
Item 1A.	Risk Factors	32
Item 1B.	Unresolved Staff Comments	74
Item 2.	Properties	74
Item 3.	Legal Proceedings	74
Item 4.	Mine Safety Disclosures	75
	PART II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	76
Item 6.	Selected Financial Data	77
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	77
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	92
Item 8.	Financial Statements and Supplementary Data	93
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	123
Item 9A.	Controls and Procedures	123
Item 9B.	Other Information	125
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	126
Item 11.	Executive Compensation	126
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	126
Item 13.	Certain Relationships and Related Transactions, and Director Independence	126
Item 14.	Principal Accounting Fees and Services	126
	PART IV	
Item 15.	Exhibits and Financial Statement Schedules	126
Item 16.	Form 10-K Summary	130
	Signatures	131

Special Note Regarding Forward-Looking Statements

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

- unanticipated safety concerns related to the use of our products;
- U.S. Food and Drug Administration (FDA) or other U.S. or foreign regulatory or legal actions or changes affecting us or our industry;
- the results of any ongoing or future legal proceedings, including but not limited to intellectual property, product liability or other litigation against us, our third-party manufacturers or other parties on which we rely or litigation against our general industry;
- any termination or loss of intellectual property rights;
- any voluntary or regulatory mandated product recalls;
- adverse developments concerning our manufacturers or suppliers or any future strategic partnerships;
- introductions and announcements of new technologies by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- successful integration of acquired operations into our ongoing business;
- announcements of regulatory approval or disapproval of our products and any future enhancements to our products;
- adverse results from or delays in clinical studies of our products;
- variations in our financial results or those of companies that are perceived to be similar to us;
- success or failure of competitive products or therapies in the markets in which we do business;
- changes in the structure of healthcare payment of our products;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- economic and market conditions in general and in the medical technology industry specifically, including the size and growth, if any, of the market, and issuance of securities analysts’ reports or recommendations;
- rumors and market speculation involving us or other companies in our industry;
- sales of substantial amounts of our stock by directors, officers or significant stockholders, or the expectation that such sales might occur;
- additions or departures of key personnel;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- the continued impact of the novel coronavirus (COVID-19) pandemic, and the related responses of the government and consumers on our business, financial condition and results of operations.

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

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

This Annual Report on Form 10-K includes our trademarks and trade names, including, without limitation, r-SNM®, Axonics SNM System® and Bulkamid®, which are our property and are protected under applicable intellectual property laws. This Annual Report on Form 10-K also includes trademarks and trade names that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K appear without the ® and ™ symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Risk Factors Summary

The following is a summary of some of the risks and uncertainties as of the date of the filing of this Annual Report on Form 10-K that could materially adversely affect our business, financial condition, and/or results of operations. You should read this summary together with the more detailed description of each risk factor contained below.

Risks Related to Our Business and Strategy

- We have incurred significant operating losses since inception, and we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability.
- Our r-SNM System was our sole product until we acquired the Bulkamid urethral bulking agent product line on February 25, 2021 and will generate the vast majority of our revenue for the foreseeable future.
- We rely on third parties for the manufacture of our products, some of them as a single source. This reliance increases the risk that we will not have sufficient quantities of our products or be able to purchase them at an acceptable cost, and reduces our control over the manufacturing process, which could delay, prevent or impair our development or sales efforts.
- We have a limited history of manufacturing and assembling our products in commercial quantities and may encounter related problems or delays that could result in lost revenue.
- We may require additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all.
- We compete against other companies, including Medtronic and Boston Scientific, 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.
- If the quality and benefits of our products do not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected.
- The size and future growth in the market for our products has not been established with precision and may be smaller than we estimate and our sales growth may be adversely affected.
- 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.
- Consolidation in the healthcare industry could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies.
- Our success will depend on our ability to retain senior management and other highly qualified personnel.
- If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our products, our commercial success may be severely hindered.
- We face the risk of product liability claims that could be expensive, divert management’s attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.
- Unfavorable global economic conditions could adversely affect our business, financial condition, or results.
- Our results may be impacted by changes in foreign currency exchange rates.
- A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business.

Risks Related to Legal Matters and Government Regulation

- Our operations are subject to extensive laws and government regulation and oversight both in the United States and internationally, and our failure to comply with applicable requirements could harm our business.
- We may not receive the necessary clearances or approvals for modifications to our products, and failure to do so would adversely affect our ability to grow our business.
- The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies.
- Failure to comply with postmarketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw our products from the market.

- We or any of our suppliers or third-party manufacturers could be forced to recall our products.
- Our products may cause or contribute to adverse medical events or serious safety issues, which could have a negative impact on us.
- Legislative or regulatory reforms in the United States or Europe may make it more difficult and costly for us to obtain regulatory clearances or approvals, or to manufacture, market or distribute our products.
- We and our suppliers are subject to various federal, state and foreign laws, including anti-corruption laws, fraud and abuse laws, privacy and security laws, transparency laws, trade regulations, and "conflict minerals" rules, 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 and thus could harm our business.
- Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system and new medical device regulations in Europe, could harm 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.

Risks Related to Intellectual Property

- Litigation or other proceedings or third-party claims of intellectual property infringement against us, including the Medtronic Litigation, or any of our current or future licensors, including AMF, could require us to spend significant time and money and could prevent us from selling our products, or affect our stock price.
- If we or any of our current or future licensors, including AMF, are unable to maintain, obtain or adequately protect our intellectual property rights, we may not be able to compete effectively in our market or we could be required to incur significant expenses to enforce or defend our rights or attempt to do the same.

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

- If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.

Risks Related to Our Common Stock

- The trading price of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.
- 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.
- We have incurred and will continue to incur significant costs as a result of being a public company, which may adversely affect our business, financial condition and results of operations.
- We are obligated to maintain proper and effective internal controls over financial reporting and any failure to do so may adversely affect investor confidence in us, and, as a result, the value of our common stock.
- Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.
- Anti-takeover provisions in our certificate of incorporation and bylaws, as well as under Delaware law, could discourage a takeover.
- 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.
- 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.

Item 1. Business.

Overview

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

SNM System

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

We estimate the global SNM market is now approximately $650 million to $700 million and believe it is a growing market that is currently about one to three percent penetrated. Until we entered the market, it was serviced by Medtronic as a single participant.

We believe our proprietary rechargeable SNM system (r-SNM System), the first rechargeable SNM system marketed worldwide, offers significant advantages, and is well positioned to capture market share and penetrate and grow this attractive market. Our r-SNM System is designed to last approximately 15 years in the human body, is only 5cc in volume, offers broad MRI access, ease of use, intuitive programmers, and the longest recharging interval among rechargeable SNM systems.

We began U.S. commercialization of our r-SNM System in the middle of the fourth quarter of 2019 after receiving approval by the U.S. Food and Drug Administration (FDA). We also have marketing approvals in Europe, Canada, and Australia for all relevant clinical indications.

During 2020 and early 2021, we received six additional FDA approvals for enhancements to our product offering, including a second-generation rechargeable implantable neurostimulator (INS) with a one-month recharging interval, a new patient remote control with SmartMRI™ technology, 3 Tesla MRI full-body conditional labeling, a second-generation recharging belt, an upgraded programmer and a third-generation INS which gives patients the ability to make broader stimulation parameter adjustments at home.

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

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

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

We believe that our r-SNM System offers similar therapeutic benefits and competitive advantages to the only other currently available SNM technologies, InterStim II and Interstim Micro, both offered by Medtronic. As a result of our long-lived implantable device, patients implanted with our r-SNM System do not need to undergo replacement surgery every three to five years, as is the case for patients implanted with InterStim II, potentially reducing the risks of surgery and associated infections. We 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. Our r-SNM System allows full-body MRI scans and head scans under certain conditions. This full-body MRI feature may allow more patients to choose SNM therapy to treat their bladder and bowel dysfunction.

We have designed and developed a proprietary method protected by patents, know-how, and trade secrets that enables us to combine ceramic and titanium to fabricate the INS enclosure of our r-SNM System. This method enables us to incorporate a significantly smaller battery and recharging coil into our INS, which enables us to provide a smaller sized implant that is half the weight of InterStim II while offering twice the recharging interval (one month vs. two weeks) as Interstim Micro. In addition, we engineered the INS to deliver constant-current stimulation, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. Our r-SNM System also includes an easy-to-use patient remote control. We also designed and custom built a clinician programmer that guides the implanting physician through electrode placement and stimulation programming.

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

We intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System. Our goals include expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary cell battery.

We focus the significant majority of our sales and marketing efforts in the United States where reimbursement for SNM therapy is well established and covered by most major U.S. insurers, including Medicare. Additionally, we hire and train sales representatives and clinical specialists with strong backgrounds and experience in SNM therapy and other neurostimulation applications, and who have existing relationships with urologists and urogynecologists. We are initially targeting the estimated top 1,000 physicians that represent a majority of the implant volume in the United States. We estimate that approximately 80% of U.S. implant volume is generated by these 1,000 physicians.

Urethral Bulking Agent

On February 25, 2021, we announced the acquisition of Contura Limited (Contura) and its Bulkamid product, a urethral bulking agent indicated for the treatment of female SUI. In consideration for the acquisition, we paid approximately $141.3 million in cash and issued 1,096,583 shares of our common stock. We may pay an additional $35 million in the event Bulkamid sales in any consecutive 12-month period exceed $50 million before December 31, 2024.

As part of the transaction, we entered into a supply agreement with Contura International A/S (Contura International) to manufacture Bulkamid for us (Manufacturing and Supply Agreement). We have a right to a technology transfer after June 30, 2022 that would enable us to insource the manufacturing of Bulkamid.

Bulkamid received a CE Mark in 2003 and a PMA from the FDA in 2020 and has been sold through a combination of a direct sales force and distributors, which we expect to continue under our ownership. The acquisition of Contura is expected to expand our international operations.

SUI is a common condition that afflicts women of all ages, with childbirth as one of the main contributing factors. SUI is caused by weakness in the pelvic floor, preventing the urethra from closing fully when sudden pressure is put on the bladder. This can allow urine to leak out during normal daily activities such as coughing, laughing, exercising, or lifting an object. SUI is different from overactive bladder. OAB, which is not related to

pelvic floor weakness, is treated with drugs, Botox or SNM. Many patients present with both SUI and UUI, referred to as mixed incontinence.

We believe the market for SUI is large and highly underpenetrated, particularly in the United States, with approximately 20 million women suffering from SUI. Similar to urinary incontinence, the majority of women with SUI are suffering in silence. We estimate that approximately 8.8 million women have sought medical treatment, most of whom were offered conservative therapy or opted for no treatment due to a lack of non-invasive treatment options with high efficacy. Similar to SNM, we believe the SUI market is poised for significant and durable growth in the years ahead.

While bulking agents have been on the market for over a decade, the bulking effect of the legacy gels has limitations. This is primarily due to difficulty in administration and the variability in the volume of gel material injected, resulting in middling satisfaction and relief for patients. Legacy bulking agents contain microparticles, which according to clinical literature, sometimes induce a chronic inflammatory response. The combination of these factors has led to modest use of legacy bulking agents and physician preference for an invasive sling procedure to treat women with SUI.

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

Bulkamid is biocompatible, consisting of 97.5% water, and does not induce a chronic inflammatory response. Bulkamid's bulking effect is aided due to the fact that the volume, of each injection is predictable, controllable, and precise. Bulkamid retains its bulking characteristics for a number of years, thereby maintaining efficacy and providing women with long lasting relief of their SUI symptoms. Bulkamid is supported by extensive clinical validation, with over 70,000 women treated to date, and generates high rates of patient satisfaction.

We believe we can leverage our expansive commercial footprint and accelerate Bulkamid's adoption in the United States. As is the case in certain European markets, such as the U.K., we believe Bulkamid will quickly become the gold standard in the U.S. for bulking agents and take share from invasive sling procedures. The new product line further increases our value to physicians as we can now offer customers best-in-class solutions for patients with various types of OAB and SUI.

Bulkamid is currently sold through a direct salesforce in the U.S., U.K., Germany, France, Nordic countries and through distributors in over 30 international markets around the world. In the United States, there are currently only five sales professionals.

The acquisition of Bulkamid is expected to be accretive to revenue growth, gross margins and operating margins in 2021 and beyond.

Our Success Factors

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

- ***Large and growing SNM market with established coverage and reimbursement.*** SNM treatment for OAB, FI, and UR is a well-established therapy. Since the first FDA-approved SNM device, the InterStim I System, was introduced in 1997, we estimate hundreds of thousands of patients have been implanted worldwide with such system and its successor InterStim II. In 2018, we believe that approximately 45,000 patients were implanted with SNM therapy, including an estimated 10,000 patients receiving replacement implants, corresponding to an approximately $650 million to $700 million global annual addressable SNM market. We estimate the global SNM market is approximately one to three percent penetrated, and we believe that the introduction of highly differentiated SNM solutions has the potential to grow the market in excess of historical size and growth rates. In addition, because SNM therapy has been widely used in patients for over 20 years in the United States, which we believe makes up nearly 90% of the sales in the global SNM market, reimbursement codes and payments are well-established, and the procedure is covered by most major U.S. insurers.

- ***Long-term solution offering material benefits to patients, physicians, and payors.*** Our r-SNM System was the first system for SNM therapy with a rechargeable INS battery that is designed to last approximately 15 years. As a result, our r-SNM System offers several benefits not found in the legacy competitive device, the InterStim II. First, patients implanted with our r-SNM System do not need to undergo replacement surgery every three to five years, as is the case for patients implanted with InterStim II, a non-rechargeable system. We believe a rechargeable system significantly improves 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. 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. Our r-SNM System was also the first SNM system to allow full-body MRI scans under certain conditions.
- ***Significant competitive and functional advantages over other approved SNM devices.*** We believe that our r-SNM System's innovative and proprietary design offers significant competitive and functional advantages over InterStim II and Interstim Micro. We believe that our r-SNM System was the first system for SNM therapy with a rechargeable INS battery that is designed to last approximately 15 years, as compared to three to five years for patients implanted with InterStim II. Our proprietary method of combining ceramic and titanium to fabricate the INS enclosure enables us to incorporate a significantly smaller recharging coil into our INS, which offers benefits such as 60% smaller size and half the weight of InterStim II, enhanced communication range with the patient programmer, and twice the recharging interval compared to Interstim Micro. In addition, our r-SNM System employs constant current which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, which we expect will provide a more consistent and reliable therapy over time and reduce patient and physician management of the therapy. Further, our r-SNM System is differentiated by significant wireless charging benefits and an easy-to-use patient remote control. Finally, we designed and custom built a clinician programmer that guides the implanting physician through electrode placement and stimulation programming.
- ***Strong clinical data.*** We have a 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 evaluated 129 patients with UUI. In the two-year results, therapy response rate was 88% of all patients initially treated. Our European study, RELAX-OAB, evaluated 51 patients that suffered from UUF and UUI. The therapeutic response rate at 12 months for the 43 patients who continued with study follow-up was 94% for test responders and 72% for all implanted patients. We intend to follow patients for at least two years for both of our clinical studies. We believe clinical data is important and will be key to driving broad-based adoption of our r-SNM System.
- ***Substantial sales and clinical field teams.*** We hire and train sales representatives and clinical specialists with strong backgrounds and experience in SNM therapy and other neurostimulation applications, and who have existing relationships with urologists and urogynecologists. We anticipate that this investment in our sales force will enable us to compete effectively and gain market share, as we expect relationships, expertise and patient outcomes will be important factors in the widespread adoption of our r-SNM System.
- ***A deep understanding of our target market.*** 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 initially focusing solely on SNM, we have been able to navigate the development and regulatory requirements for our r-SNM System in an efficient manner.
- ***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 the Alfred E. Mann Foundation for Scientific Research (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 December 31, 2020, we own 32 issued U.S. patents and 89 issued foreign patents, and 19 pending U.S. patent applications and 41 pending foreign patent

applications. We also license from AMF 30 issued U.S. patents and three pending U.S. patent applications, as well as 65 issued foreign patents and 10 pending foreign patent applications. Issued patents owned or used by us will expire between 2021 and 2040.

- ***Large and underpenetrated SUI market.*** SUI is a common condition that affects approximately 20 million women. Approximately 16% of adult women suffer from SUI at some point in their lives. It affects women of all ages but becomes more prevalent with age. It can have a significant impact on daily life, affecting activities, relationships, and emotional well-being. Many women are not aware of bulking agents and we see the SUI market as poised for significant and durable growth in the years ahead. We believe that legacy bulking agents have not achieved widespread adoption due to limited efficacy. Legacy gels contain particulate matter and achieve their bulking effect through an inflammatory response in the patient's body. In addition, we believe urethral sling procedures will become less common in treating SUI due to their invasive nature and the potential for adverse events.
- ***Substantial opportunity to capture market share with Bulkamid.*** We believe Bulkamid is a next-generation technology that has distinct advantages over legacy bulking agents and urethral sling procedures. Bulkamid is a non-particulate, biocompatible hydrogel whose bulking effect is linked to the volume of gel injected into the urethral wall, as opposed to competitive bulking agents that achieve bulking through their microparticles and the body's inflammatory reaction to the particles. We believe we can increase sales of Bulkamid by raising patient awareness and highlighting its excellent clinical results. With Bulkamid, we can now offer customers best-in-class solutions for both OAB and SUI. Bulkamid procedures are done by the same physicians that perform SNM procedures and we expect to leverage our existing relationships to drive adoption of Bulkamid.
- ***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 effective and long-term solutions to treat urinary and fecal incontinence. To achieve this goal, we are pursuing the following strategies:

- ***Continue to promote awareness of our r-SNM System among healthcare providers.*** We believe that of the approximately 47,000 physicians addressing OAB and FI in the United States, only approximately 2,000 are trained to perform, or are actively performing, SNM procedures. In the near-term, we plan to focus on converting physicians who represent a majority of the implant volume in the United States to switch to our r-SNM System. We intend to help physicians in their direct-to-patient outreach and are pursuing our own direct-to-patient marketing initiatives. We believe this will expand the number of patients undergoing SNM procedures.
- ***Continue to develop a commercialization infrastructure with a dedicated direct sales team.*** We intend to focus the significant majority of our sales and marketing efforts in the United States since we believe that nearly 90% of the annual global SNM sales are generated in this market. Our priority is to target high-volume implant centers. To achieve our commercialization goals, we plan to continue to hire and train sales representatives and clinical specialists, and to provide them with sufficient resources to achieve success.
- ***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 also include expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary cell battery.
- ***Further penetrate our initial target market by promoting patient and practice awareness.*** Currently, we estimate that approximately one percent of the four million OAB and FI patients that make up the annual global addressable SNM market are implanted with an SNM device. We believe that there are several factors that influence this light penetration of the market. First, although patients may be familiar with SNM as an alternative therapy, patients who elect not to have the procedure do so because of the limitations of the technology in place when we entered the market, such as the potential for multiple INS replacement

surgeries and the large device size. Second, we believe there is a large potential patient population that suffers from OAB and/or FI and is unaware of third-line therapies such as SNM. We believe that a very low percentage of physician specialists that treat patients with symptoms of OAB and/or FI are actively performing SNM procedures. We intend to educate physicians that are unfamiliar with or do not utilize SNM therapy on the benefits on SNM therapy and the advantages of our r-SNM System. We also intend to increase physician and patient awareness through physician engagement, direct patient outreach, and continued publication of scientific data in peer reviewed journals.

- ***Expand our product offerings with complementary products in our market.*** We believe our acquisition of Bulkamid is highly synergistic and positions us to become a global leader in urinary incontinence solutions. We expect to leverage our existing commercial footprint of over 220 sales and clinical specialists in the U.S. and Europe who call on urogynecologists and urologists for SNM, the same physicians who treat SUI. We also believe that extending our urology platform to offer solutions for both OAB and SUI will enhance our value proposition and drive additional SNM sales. Bulkamid is a unique, clinically differentiated bulking agent that we believe addresses the shortcomings of existing particulate-based bulking agents while also offering an alternative to patients who desire to avoid sling surgery and instead opt for a minimally invasive solution. Bulkamid has generated extensive clinical validation and a strong safety profile, with over 70,000 women treated to date.

Our Markets

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

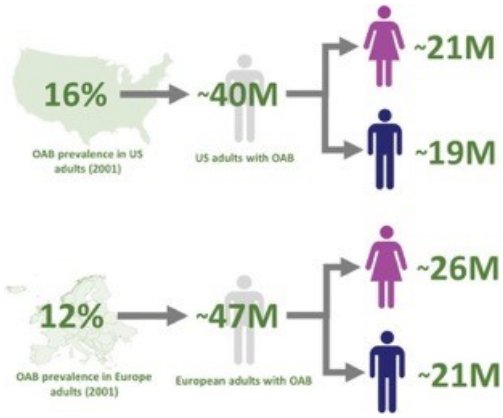
The market for SNM therapy is large and growing. We believe that the global SNM market is now approximately $650 million to $700 million, which we believe is comprised of sales of SNM systems for the treatment of UUI, UUF, FI, and UR, and is growing at an approximate rate of 8% year-over-year. We believe this represents approximately 45,000 patient implants, including an estimated 10,000 patients receiving replacement implants, with nearly 90% of sales in this market being generated in the United States and approximately 85% of sales revenue coming from new implant volume. Further, we estimate that the global annual addressable SNM market is presently approximately one to three percent penetrated. We estimate the global annual SNM market will continue to increase for the foreseeable future driven by increased awareness and education of SNM as a therapy alternative, greater expectations for quality of life, and improved patient attitudes toward receiving medical attention. In addition, market growth could accelerate due to more than one medical device company being focused on this market, new innovation for SNM therapy, and other potential products being introduced to physicians and patients. We believe that this represents a compelling opportunity for our r-SNM System to capture market share and further penetrate and grow the existing market.

The market for SUI therapy is large and highly underpenetrated, with approximately 20 million women suffering from SUI in the United States. The majority of women with SUI are suffering in silence. We estimate that approximately only 8.8 million women have sought medical treatment, most of whom were offered conservative therapy or opted for no treatment due to a lack of non-invasive treatment options with high efficacy. Further, we estimate that on an annual basis, there are 25,000 urethral bulking agent treatments and 125,000 pelvic floor sling surgeries performed.

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 (CDC), 11 states in 2000 had prevalence of obesity that exceeded 22% and this increased to 36 states that exceeded 26% by 2015. The CDC saw similar conclusions with the increase in diabetes prevalence, where in 2000, approximately half of the states had a prevalence of less than six percent, and by 2015, 27 states had exceeded nine percent.

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

The urgency to urinate associated with OAB may be accompanied by a combination of several symptoms, including abnormally frequent urination, or frequency, that is typically defined as urinating eight or more times per day, involuntary leakage of urine, or incontinence, and the disruption of sleep to wake up and pass urine, or nocturia. The combination and severity of OAB symptoms varies from person to person. UUF is characterized by the sudden need to urinate eight or more times per day and, when this symptom is not accompanied by any other symptoms,

does not include the involuntary leakage of urine. UUI is characterized by the sudden need to urinate accompanied by the involuntary loss of urine, regardless of frequency. Non-obstructive UR is the inability to empty the bladder without an obstruction, such as prostate enlargement or a stricture.

The prevalence of OAB between women and men is generally similar, however, it varies by subtype. Women are more likely to suffer from UUI than UUF, although the difference is not substantial. In contrast, men are much more likely to suffer from UUF than UUI. Incidence by age also varies between men and women, as women often develop UUI at much younger ages than men. UUI symptoms in women ranging in age from 40 to 65 years old are often associated with childbirth or menopause, while prostate enlargement, which is frequently associated with aging, is a leading cause of UUF symptoms in men. These age and gender differences are significant because they may impact who seeks treatment for symptoms of OAB. Individuals with UUI are more likely to seek treatment due to the impact of incontinence on quality of life, and younger individuals are less likely to dismiss symptoms of OAB as an expected and acceptable consequence of aging. As a result, women are more likely to seek treatment for symptoms of OAB than men.

Symptoms consistent with a diagnosis of OAB can develop due to a variety of underlying causes. When a patient consults a physician for the treatment of their symptoms related to OAB, the physician will first undertake a differential diagnosis in an attempt to determine the underlying cause of OAB. Underlying issues that can cause OAB include neurological diseases and injuries, obstructions, bladder abnormalities, and other issues.

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

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

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

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

Overview of Fecal Incontinence

FI is the inability to control bowel function, causing involuntary or accidental leakage from the rectum. Stimulation of the sacral nerves can reduce incontinence episodes, urgency, and frequency in people suffering from FI, and is an approved therapy for the treatment of FI in the United States and Europe. Moreover, a significant population of people suffering from FI also exhibit symptoms of OAB. SNM therapy can alleviate symptoms in patients suffering from either or both OAB and FI. We believe approximately 60% of people with FI exhibit idiopathic symptoms or experience FI as result of obstetric or surgical injury or other prior trauma, all of which can be treated with SNM therapy.

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

According to the American National Health and Nutrition Examination Survey program of 2005 through 2006, approximately 8.3% of the adult population in the United States exhibited symptoms of FI. Based on the estimate of the United States population in 2014 of approximately 221 million adults, approximately 18 million adults in the United States exhibited symptoms of FI. In this survey, FI prevalence was assessed as the occurrence of at least one incontinence episode during the past month. Weekly episodes were estimated to occur in 2.7% of the population, and daily episodes in 0.9%. In addition, according to The National Institute for Health and Care Excellence in the United Kingdom, of the approximately 391 million adult population in Europe in 2007, between 1.0% and 10.0% exhibited symptoms of FI. Based on this data, we have assumed that 5.0% of the adult population in Europe at that time, or approximately 20 million people, exhibited symptoms of FI.

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

If the physician is able to determine that FI is caused by a clear, underlying disease, such as inflammatory bowel disease, the physician will then prescribe a care pathway to treat the underlying disease and alleviate the symptoms. Patients with FI caused by past trauma, mainly from obstetric damage, represent the majority of candidates for treatment of FI with SNM therapy. Additionally, in the absence of an identified underlying cause of FI symptoms, the patient is considered to have idiopathic FI. These idiopathic patients, who make up 10% of women suffering from FI and 7% of men suffering from FI, are also ideal candidates for SNM therapy.

Overview of Stress Urinary Incontinence

SUI is a common condition that afflicts women of all ages, with childbirth as one of the main contributing factors. SUI is caused by weakness in the pelvic floor, preventing the urethra from closing fully when sudden pressure is put on the bladder. This can allow urine to leak out during normal daily activities such as coughing, laughing, exercising, or lifting an object. The first-line treatment options for SUI begin with lifestyle changes and continence pessaries. SUI lacks pharmacologic treatments, with patients next advancing to urethral bulking agents, pelvic floor sling surgery or colpsosuspension.

Path to Treatment

Overactive Bladder

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

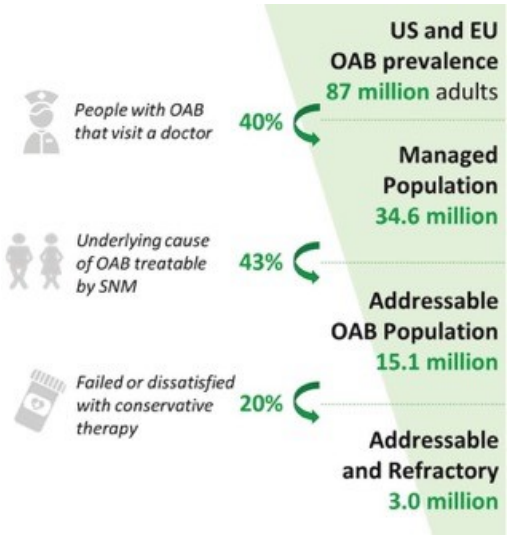
Of the approximately 15.9 million patients who seek medical attention in the United States for the treatment of symptoms of OAB, we believe that approximately 6.8 million are addressable with SNM therapy. Similarly, in

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

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

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

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



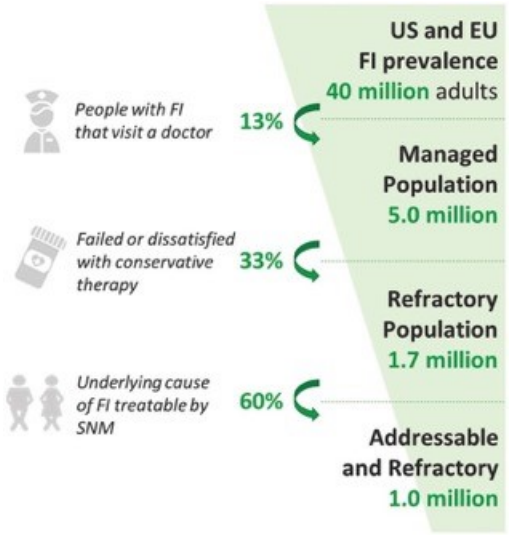
Fecal Incontinence

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

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

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

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



Current Treatments for OAB and Limitations

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

- *First-line therapy*: behavioral changes, including conservative treatment options such as diet, exercise, timed voiding, pelvic floor exercises, and biofeedback;
- *Second-line therapy*: drug therapy, including two classes of OAB drugs, anti-muscarinics and beta-3 adrenergic agonists, with patients often trying multiple drugs; and
- *Third-line therapy*: minimally invasive therapy consisting of SNM, BOTOX injections and 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 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 UUI by the FDA in 1997 and 1999 for UUF, respectively. These systems have been implanted in hundreds of thousands of patients worldwide, with a majority of all implants having taken place in the United States. In 2018, approximately 45,000 patients were implanted with these systems, including an estimated 10,000 patients receiving replacement implants.

BOTOX Injections

BOTOX injections into the bladder muscle were approved for treatment of symptoms of OAB by the FDA in 2013. BOTOX is injected through a cystoscopic procedure in a clinician’s office or the outpatient surgery setting, and BOTOX treats OAB by blocking the signal from the bladder nerves to the bladder muscle. Key adverse events include recurrent urinary tract infections and self-catheterization due to inability to void. BOTOX injections are typically required every six to 12 months to maintain reduction of OAB symptoms. We believe the frequent need for injections and the adverse event profile are deterrents to initial and long-term preference for BOTOX injections, as evidenced by an approximately 60% rate of cessation of BOTOX injections at three years, according to a retrospective study by Mohee et al. 2012.

Percutaneous Tibial Nerve Stimulation

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

Our r-SNM System

We believe that our proprietary r-SNM System provides a minimally invasive, effective, and long-lasting solution for SNM therapy to treat patients with bladder and bowel dysfunction. We have marketing approvals in Europe, Canada, and Australia for all relevant clinical indications. Our initial PMA application for our r-SNM System for the treatment of FI was approved by the FDA on September 6, 2019, and our PMA application for our r-SNM System for the treatment of OAB and UR was approved by the FDA on November 13, 2019.

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

Implantable Components for Patient

- Miniaturized rechargeable INS, which houses the electronics for the device. It is five cubic centimeters and is intended to provide one month of battery life between charges under normal use conditions.
- Tined four-electrode lead, which delivers current-controlled stimulation to the targeted sacral nerve. The tines help anchor the lead in its desired position.

Implantable Neurostimulator

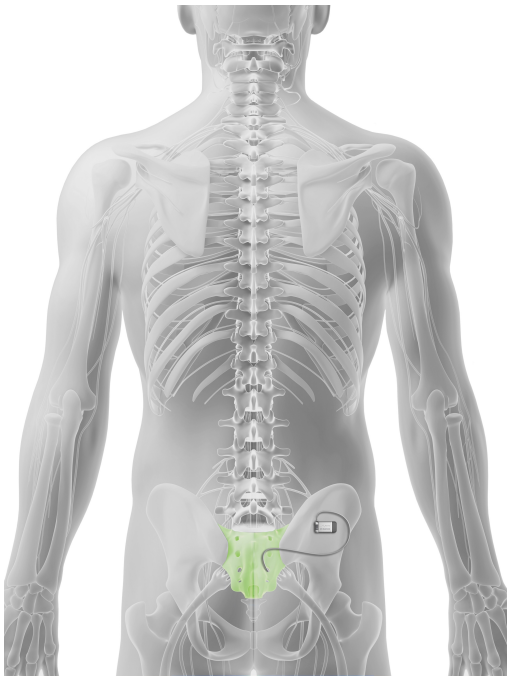
External Components for Patient

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

Wireless Charging Device

Patient Remote Control

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



Benefits of our r-SNM System

We believe that our innovative and proprietary r-SNM System offers several competitive advantages as compared to the legacy SNM system, InterStim II. Our device was the first SNM System to offer the following important benefits:

- **Long-term solution**. The battery is designed to last 15 years, compared to 3-5 years for the non-rechargeable Interstim II.
- **Material benefits to physicians and payors.** We believe our r-SNM System has the potential to enable physicians and facilities to utilize their resources more efficiently and significantly reduce overall costs to the healthcare system, due to the need for less replacement surgeries compared to InterStim II.
- **Small and lightweight implantable neurostimulator.** Our INS is approximately 60% smaller than and half the weight of InterStim II.
- **Constant current.** Our r-SNM System delivers constant-current stimulation, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body and we believe provides a more consistent and reliable therapy.

In addition, we believe our r-SNM System offers many additional competitive advantages compared to the InterStim product line, including the InterStim Micro, our competitor's new rechargeable device:

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

- **Simplified physician implantation and programming.** Our clinician programmer guides the implanting physician through electrode placement and stimulation programming and enables physicians to access key data from the patient's INS.
- **Broad MRI conditions.** Our r-SNM System allows for 1.5T and 3T full-body MRI scans under broad conditions. For example, 1.5T full-body MRI scans can be done in normal operating mode with no additional whole-body specific absorption rate limitation.
- **Clinically proven results.** Our r-SNM System is the only rechargeable SNM System with clinical data to support its safety and efficacy. Two-year results from our clinical study show that 93% of patients achieved clinically significant improvements.

Overview of our External Trial System

Our external trial system (ETS) can be used during an evaluation period by a physician to determine if a patient is a good candidate for SNM therapy. This system includes a disposable external stimulation device, a disposable implantable lead, and a patient remote control. The external stimulation device is comprised of a temporary, non-rechargeable, current controlled pulse generator. The temporary implantable lead has a single electrode. In addition, our ETS can be used for a bilateral percutaneous nerve evaluation trial or a tined lead evaluation trial. In July 2018, we received the CE Mark for our ETS, and in September 2019, we received FDA approval for our ETS.

Overview of our Physician Tools

We provide physicians with a clinician programmer and a surgical tool kit to assist them while implanting our r-SNM System. Our clinician programmer also allows physicians to connect to a patient's INS, while the patient is in the physician's care, to access key therapy data that is stored and maintained on the INS.

Clinician Programmer

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

Clinician Programmer

Surgical Tool Kit

The single-use surgical tool kit provides the physician with the tools necessary for the r-SNM System implant procedure. The tools provided are familiar for physicians experienced in SNM implants and follow the established surgical techniques for the implant.

Treatment with our r-SNM System

Patient Selection

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

SNM therapy for bowel dysfunction is indicated for patients who are not candidates for more conservative treatments. The therapy is not indicated for pregnant women, or pediatric use.

Implantation

Before receiving our r-SNM System, a patient in the United States typically undergoes an external trial period.

External Trial Period

The short external trial procedure, which typically lasts approximately 30 minutes, is generally performed in the office or outpatient setting and typically involves a percutaneously placed lead, which a physician implants near the targeted sacral nerve using a needle, with the location confirmed utilizing fluoroscopy and intraoperative muscle responses evoked by test stimulation. The lead is then connected to a temporary, disposable external trial system which provides stimulation for the therapy. The trial period can last between a few days and several weeks after which the physician evaluates the effectiveness of SNM therapy through several measures, including bladder or bowel episodes and patient satisfaction. Approximately 60-90% of patients proceed from trial stimulation to permanent implant depending on the trial type and patient selection.

Permanent Implant

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

Activation and Programming

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

Our Clinical Results and Studies with our r-SNM System

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

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

- 113 of the 121 implanted patients completing the two-year visit, or 93%, were therapy responders. Of the 129 patients initially treated, 88% were therapy responders at two years (113 out of 129);
- 93 of the 113 therapy responses, or 82%, had a ≥75% reduction in urgency incontinence episodes; and
- 94% of patients reported being “satisfied” with the therapy; and
- No serious device-related adverse events have been reported.

Our European RELAX-OAB study that began in June 2016 evaluated 51 patients at seven sites in Europe that suffered from OAB subtypes UUI and/or UUF. The 12-month results were published in the peer reviewed *Journal of Neurourology and Urodynamics* in January 2019. All patients were evaluated to determine if they were therapy responders, which was defined as showing at least a 50% reduction in the number of average leaks or voids per day or a reduction to less than eight voids per day, in each case on a three-day bladder diary, at various times post-implant. We are following patients out to two years in this study and may follow patients out to five years at selected study sites.

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

- The study has completed one-year follow-ups and two-year follow-ups;
- Therapy responder rate at 12 months for the 43 patients who continued with study follow-up was 94% for test responders and 72% for all implanted patients;
- At 12 months, 84% of test responders and 77% of all implanted patients were “very” or “moderately” satisfied with the therapy provided by our r-SNM System; and
- No serious device-related adverse events have been reported.

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

Our Bulkamid Product

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

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

The Bulkamid procedure is minimally invasive, with no cuts or incisions necessary, and typically takes around 10 to 15 minutes. It usually is performed in an outpatient facility or day surgery unit under a local anesthetic and the patient is able to return home the same day. The injections are made into 3 to 4 locations in the urethral wall; the total volume injected is 1.5 to 2 mL, equivalent to slightly less than half a teaspoon. It is a simple procedure that is easy for physicians to learn.

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

Patients who undergo Bulkamid treatment are likely to be free from unwanted urinary leakage or at least have significantly fewer episodes of urinary leakage. In Bulkamid clinical studies, women were asked how effective their treatment was 12 months after their initial injection. Over three quarters of women reported that their incontinence was either cured or improved and approximately two-thirds of women were dry. Bulkamid clinical studies have also shown that most of the women treated over 7 years ago still report benefit.

Over 70,000 women with stress urinary incontinence have been treated with Bulkamid across 25 countries over the last 15 years. During that time, a low number of complications or adverse events have been reported and there have been no reported long-term complications.

Sales and Marketing

We are primarily focused on commercializing our products in the United States, which accounts for the vast majority of SNM sales worldwide. We have established a significant commercial infrastructure, with over 220 sales personnel and clinical specialists and we continue to make significant investments to build our commercial organization to market and support our products. When making hiring decisions for these roles, we prioritize individuals with strong sales backgrounds and experience in SNM therapy and other neurostimulation applications, and who also have existing relationships with urologists and urogynecologists. We expect to focus the significant majority of our sales and marketing efforts in the United States where reimbursement for SNM therapy is well established and covered by most major U.S. insurers, including Medicare.

Through our specialized and dedicated direct sales organization, we are targeting the approximately 2,000 urologists, urogynecologists and colorectal surgeons who are trained and have experience performing SNM procedures. Our particular focus is on the estimated top 1,000 implanting centers that represent a majority of the implant volume in the United States. We estimate that approximately 80% of U.S. implant volume is generated by these 1,000 implanting centers.

In order to support our direct sales team, we have approximately 90 clinical support staff as of December 31, 2020. This clinical staff is 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 are promoting 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 expand our awareness raising activities, including publication of scientific data in peer reviewed journals and education of physicians who are not familiar with or do not utilize SNM therapy. We may also engage in broad marketing initiatives in jurisdictions where we are permitted to do so.

Our main commercial priority is the United States where we began commercializing and marketing our r-SNM System and generate revenue from product sales. In November 2018, we launched a limited commercial effort in Europe, where we currently have five dedicated sales representatives. We do expect to expend capital resources pursuing commercial operations in Europe, Canada and Australia, where we have marketing approvals for OAB, FI, UR and SUI, but the amount and timing of which will depend on a variety of factors, including the size of the developed market for SNM therapy and bulking agents, burdens to entry and other region- and country-specific factors.

The acquisition of Contura leverages our existing commercial footprint of over 220 sales and clinical specialists in the U.S. and Europe that call on urogynecologists and urologists. Bulkamid is currently sold through a direct salesforce in the U.S., U.K., Germany, France, Nordic countries and in addition, through distributors in over 30 international markets around the world. In the United States, there are currently five sales professionals.

Third-Party Coverage and Reimbursement

In the United States, we derive revenue from the sale of our products to hospitals and ambulatory surgical centers, which typically bill various third-party payors, including Medicare, Medicaid, private insurance companies, health maintenance organizations and other healthcare-related organizations. In addition, we expect that any portion of the costs and fees associated with our r-SNM System that are not covered by these third-party payors, such as deductibles or co-payments, will be billed directly to the patient by the provider. Third-party payors require physicians and hospitals to identify the product and service for which they are seeking reimbursement by using Current Procedural Terminology (CPT) codes, which are created and maintained by the American Medical Association (AMA). As SNM therapy has been widely used in patients for over 20 years in the United States, reimbursement codes and payments are well-established and the procedure is covered by Medicare, Medicaid and private health insurance plans. Similarly for urethral bulking agent treatments, reimbursement codes and payments are well-established and the procedure is covered by Medicare, Medicaid and private health insurance plans.

Physician reimbursement under Medicare is generally based on a defined fee schedule (the Physician Fee Schedule), through which payment amounts are determined by the relative value of the service rendered by the physician. Medicare generally provides reimbursement to hospitals and ambulatory surgical centers for SNM therapy under the hospital outpatient prospective payment system and the Ambulatory Surgical Center Payment

System, respectively, which reimburse to the hospital or ambulatory surgical center, as applicable, a bundled amount generally intended to cover all facility costs related to procedures performed in the outpatient setting. The typical Medicare payment for facility and physician services for an SNM trial and full system implant ranges from approximately $22,000 to approximately $27,400, which covers the cost for the devices and the implantation procedures.

Our r-SNM System and the associated procedures are eligible for payment under the existing CPT codes typically used for SNM therapy, including CPT 64581 for transforaminal implantation of a lead near the sacral nerve and CPT 64590 for insertion or replacement of a peripheral or gastric neurostimulator, which includes a neurostimulator for SNM therapy. Reimbursement rates vary based on several factors, including but not limited to the payor, geographic location, the procedure performed, contract terms, the facility in which the procedure is performed and other factors.

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

Outside the United States, reimbursement levels vary significantly by country and by region, particularly based on whether the country or region at issue maintains a single-payor system. SNM therapy is eligible for reimbursement in Canada, Australia and certain countries in Europe. Annual healthcare budgets generally determine the number of SNM systems that will be paid for by the payor in these single-payor system countries and regions. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. Some countries or regions may require us to gather additional clinical data before granting coverage and reimbursement for our r-SNM System.

Research and Development

We intend to continue to invest in research and development activities focused on improvements and enhancements to our r-SNM System to improve patient outcomes and further expand patient access to our r-SNM therapy. Research and development expenses were approximately $29.2 million, $20.2 million, and $19.4 million for the years ended December 31, 2020, 2019, and 2018, respectively. Our goals include expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary cell battery.

Manufacturing and Supply

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

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

We inspect, test, and assemble our r-SNM System under strict manufacturing processes supported by internal policies and procedures. We perform our own final quality control testing of each r-SNM System. However, we do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract

manufacturing partners for compliance with current Good Manufacturing Practice (cGMP) regulations applicable to our r-SNM System.

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

For our off-the-shelf components, we do not have long-term supply agreements with many of our third-party manufacturers, and we purchase certain components of our r-SNM System on a purchase order basis. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. We do not currently have arrangements in place for redundant supply of certain components of our r-SNM System. If our current third-party manufacturers cannot perform as agreed, we may be required to replace those manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture these components, we may incur added costs and delays in identifying and qualifying any such replacement. We believe our manufacturing capacity is sufficient to meet global market demand for our r-SNM System for the foreseeable future.

As previously discussed, and pursuant to the Manufacturing and Supply Agreement, Contura International manufactures all of the Bulkamid that we sell. We have rights to a technology transfer after June 30, 2022 that would enable us to insource the manufacturing of Bulkamid. Under the Manufacturing and Supply Agreement, Contura International is responsible for obtaining and maintaining all necessary permits, licenses, approvals and authorizations required for the manufacture and sale of Bulkamid. The Manufacturing and Supply Agreement is subject to certain maximum purchase amounts of Bulkamid, which we believe are sufficient to meet the projected global demand for Bulkamid.

Competition

We believe our products are designed to offer several needed improvements for patients, physicians, and payors. However, the medical technology industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants.

We consider our primary competition to be implantable SNM devices offered by Medtronic. Medtronic's InterStim II and Interstim Micro are currently the only other implantable SNM devices approved for commercial sale in the United States by the FDA. We also compete with other third-line treatments, such as BOTOX injections, a product sold by Allergan plc, PTNS, as well as more invasive surgical treatment options, and drugs for the treatment of OAB and FI. We also face competition from Boston Scientific for the treatment of SUI with its own competitive hydrogel. In addition, emerging businesses may be in the early stages of developing additional products or therapies designed to treat OAB, FI or SUI.

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

- company, product and brand recognition;
- history of product use and physician familiarity with products and treatments;
- regulatory approvals and approved indications;
- product safety, reliability and durability;
- INS size, rechargeability and battery life;
- full-body MRI scan safety;

- quality and volume of clinical data;
- effective marketing to and education of patients, physicians and hospitals;
- product ease of use and patient comfort;
- physician implantation and programming process;
- sales force experience and market access;
- product support and service;
- technological innovation, product enhancements and speed of innovation;
- pricing and revenue strategies;
- procedure costs to patients and the overall healthcare system; and
- dedicated practice development.

Intellectual Property

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

We own numerous issued patents and pending patent applications that relate to our r-SNM System and several issued patents and patent applications were licensed from AMF in 2013 pursuant to the License Agreement. As of December 31, 2020, we own 32 issued U.S. patents and 89 issued foreign patents, and 19 pending U.S. patent applications and 41 pending foreign patent applications. We also license from AMF 30 issued U.S. patents and three pending U.S. patent applications, as well as 65 issued foreign patents and 10 pending foreign patent applications. Issued patents owned or used by us will expire between 2021 and 2040.

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

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

AMF License Agreement

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

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) a minimum annual royalty (the Minimum Royalty), payable quarterly. The Minimum Royalty automatically increases each year, subject to a maximum amount of $200,000 per year. During the years ended December 31, 2020, 2019, and 2018, we have recorded royalties of $4.4 million, $0.6 million, and $0.1 million, respectively. We have 60 days to pay AMF the royalty amount due under the License Agreement, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

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

Government Regulation Applicable to Us

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

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

FDA Premarket Clearance and Approval Requirements

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

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

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

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

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which may affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may require no clinical data or less extensive clinical data than the original PMA or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new 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.

Postmarket Regulation - United States

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

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

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

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

- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to permit the export or import of our products or future product candidates; or
- criminal prosecution.

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

Regulation of Medical Devices in the EEA and the U.K.

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

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

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

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

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

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

If satisfied that the AIMD or other medical device conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of

conformity (see above). The manufacturer may then apply the Conformité Européenne (CE) mark to the device, which allows the device to be legally placed on and traded within the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the product.

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

On April 5, 2017, the European Parliament adopted the Medical Devices Regulation (Regulation 2017/745), which will repeal and replace both AIMD and Medical Devices Directives. The Medical Devices Regulation is directly applicable in the EEA. This is intended to eliminate current differences in the regulation of medical devices among EEA countries. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

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

United Kingdom's Vote to Leave the EU (Brexit)

The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to EU markets. 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 and implementation 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, Brexit will likely affect European and worldwide economic or market conditions, 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 the EEA countries, Australia, Canada, and other foreign countries in which we may sell our r-SNM System, including in the areas of:

- design, development, manufacturing and testing;
- product standards;
- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;

- labeling requirements;
- content and language of instructions for use;
- clinical studies;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;
- postmarket surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement; and
- necessity of testing performed in country by distributors for licensees.

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

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

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

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

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

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 in order to have committed a violation. Moreover, government authorities may argue 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 U.S. Anti-Kickback Statute may result in civil monetary penalties up to $102,522 (in 2019) for each violation, plus up to three times the remuneration involved. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. In addition, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid.

Government authorities may contend that we are liable under the U.S. Anti-Kickback Statute because of the intentions or actions of the parties with whom we do business, if we acted with deliberate ignorance or reckless disregard. The majority of states also have anti-kickback laws that establish similar prohibitions, and in some cases, may apply more broadly.

The U.S. 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. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act, if a person acts with deliberate ignorance or reckless disregard.

In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the U.S. civil False Claims Act in the name of the government and share in the proceeds of any recovery. Penalties for U.S. civil False Claim Act violations include fines ranging from $11,181 to $22,363 for each false claim, plus up to three times the amount of damages sustained by the federal government. More critically, a violation may provide the basis for exclusion from federal healthcare programs. 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.

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

Anti-Bribery and Corruption Laws

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

FCC Regulation

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

Data Privacy and Security Laws

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

For example, the U.S. Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), establishes uniform standards governing the use and disclosure of protected health information (PHI) and requires healthcare providers, called "covered entities", to maintain certain safeguards to protect the privacy and security of PHI. HIPAA also requires

business associates (independent contractors or agents of covered entities that create, receive, maintain, or transmit PHI on behalf of a covered entity) to enter into business associate agreements with the covered entity. These agreements require the business associate to safeguard the covered entity's PHI against improper use and disclosure.

Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties 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 can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits alleging negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance with the HIPAA privacy and security standards.

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

The GDPR became applicable on May 25, 2018, replacing the previous data protection laws issued by each EU member state under the Directive 95/46/EC. Unlike the Directive, the GDPR is directly applicable in each EU Member State, resulting in a more uniform application of data privacy laws across the EU. Like the previous Directive, the GDPR requires that personal data may only be collected for specified, explicit and legitimate purposes based on legal bases for processing set out in the GDPR and local laws, and may only be processed in a manner consistent with those purposes. Personal data must be secure, not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection and must not be kept for longer than necessary for the purposes of collection. In addition, the GDPR also limits the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA. In particular, in order to process such data, explicit consent to the processing (including any transfer) is usually required from the data subject (being the person to whom the personal data relates).

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

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

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. The Affordable Care Act 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.

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.

Impact of COVID-19

The COVID-19 pandemic negatively impacted our sales in 2020, by significantly decreasing and delaying the number of procedures performed using our r-SNM System, and we expect that the pandemic could continue to negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our r-SNM System decreased significantly as healthcare organizations in the United States and globally, including in Europe and Canada, have prioritized the treatment of patients with COVID-19 or have altered their operations to prepare for and respond to the pandemic. Specifically, substantially all of the procedures using our r-SNM System were postponed or cancelled from middle of March 2020 through May 2020, but order flow began a gradual recovery in May 2020 and continued to improve in the second half of 2020.

To protect the health of our employees, their families, and our communities, we have restricted access to our offices to personnel who must perform critical activities that must be completed on-site, limited the number of such personnel that can be present at our facilities at any one time, requested that many of our employees work remotely, and implemented travel restrictions. These restrictions and precautionary measures have not adversely affected our operations. The full extent of COVID-19's effect on our operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and additional protective measures implemented by the governmental authorities, all of which are uncertain and difficult to predict considering the rapidly evolving landscape. However, if the pandemic continues to evolve into a long-term severe worldwide health crisis, there could be a material adverse effect on our business, results of operations, financial condition, and cash flows.

Human Capital Resources

As of December 31, 2020, we had 416 employees. Of this total, 9 were employees based outside of the U.S. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

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

Company Information

We were incorporated in the State of Delaware in March 2012 under the name "American Restorative Medicine, Inc." In August 2013, we changed our name to Axonics Modulation Technologies, Inc. and commenced our operations in late 2013 when we entered into the License Agreement. Our principal executive offices are located at 26 Technology Drive, Irvine, California 92618 and our telephone number is (949) 396-6322. Our website is www.axonics.com. The information contained on or that can be accessed through our website is not incorporated by reference into this Annual Report on Form 10-K.

Available Information

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

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report on Form 10-K, including our consolidated financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of these risks could have a material and adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. Certain statements contained in this section constitute forward-looking statements. See the information included in "Special Note Regarding Forward-Looking Statements" in this Annual Report on Form 10-K. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Business and Strategy

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

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

We have not yet derived sufficient revenues to support our operations, as our activities prior to 2020 have consisted primarily of investing in our commercial operations, developing our technology, and conducting clinical studies. As a result, we have recorded net losses of $54.9 million, $79.9 million, and $32.5 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $234.5 million. To date, we have financed our operations primarily through equity financings.

We expect that our operating expenses will continue to increase as we (i) continue to build our commercial infrastructure, (ii) develop, enhance, and expand the commercialization of our r-SNM System in the United States, (iii) potentially seek additional FDA regulatory approvals for our r-SNM System or other future product candidates in the United States, (iv) increase our commercialization efforts internationally and (v) incur additional operational costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

We expect that sales of our r-SNM System will account for a 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 currently represents the vast majority of our sales, and we are substantially dependent on the success of our r-SNM System.

Until we acquired the Bulkamid product on February 25, 2021, our r-SNM System was our sole product, and we expect it will drive the vast majority of our sales for the foreseeable future. As a result, we are substantially dependent on its success. We expect that it will take time for us to increase adoption of our Bulkamid products. Successfully commercializing medical devices such as ours is a complex and uncertain process. Our commercialization efforts depend on the efforts of our management and sales team, our third-party manufacturers and suppliers, physicians and hospitals, and general economic conditions, among other factors, including the following:

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

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

We hire and train sales representatives and clinical specialists with strong backgrounds and experience in SNM therapy and other neurostimulation applications, and who have existing relationships with urologists and urogynecologists. However, we expect that our sales force will require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us. If our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent any of our sales force is comprised of personnel hired from our competitor, we may have to wait until applicable non-competition provisions have expired before deploying such

personnel in restricted territories or incur costs to relocate personnel outside of such territories. This may subject us to allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Addressing such allegations would be costly both in terms of time and resources. Any of these risks may adversely affect our business.

The integration of Contura's businesses may be more difficult, time-consuming or costly than expected. Synergies and other anticipated benefits may not be realized within the expected time frames, or at all.

Our ability to realize the anticipated benefits of the acquisition of Contura and its subsidiaries depend, to a large extent, on our ability to integrate the acquired business in a manner that facilitates growth opportunities and achieves projected standalone revenue growth trends without adversely affecting revenues and investments in future growth. The failure to meet the challenges involved in combining our and Contura's businesses and to realize the anticipated benefits from such combination, including expected synergies, could adversely affect our results of operations. The overall combination of our businesses may also result in material unanticipated problems, expenses, liabilities, competitive responses, and loss of customer and other business relationships. The difficulties of combining the operations of the companies include, among others: the diversion of management attention to integration matters; difficulties in integrating operations and systems; challenges in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the two companies; difficulties in integrating employees and attracting and retaining key personnel, including talent; challenges in retaining existing, and obtaining new customers, suppliers, employees and others; difficulties in achieving anticipated cost savings, synergies, business opportunities, financing plans and growth prospects from the combination; difficulties in managing the expanded operations of a significantly larger and more complex company; challenges in continuing to develop valuable and widely accepted content and technologies; contingent liabilities that are larger than expected; and potential unknown liabilities, adverse consequences and unforeseen increased expenses associated with the acquisition of Contura.

Even if our operations are integrated successfully, the full benefits of the acquisition of Contura, including anticipated synergies, cost savings or sales or growth opportunities, may not be realized, and these benefits may not be achieved within any anticipated time frame or at all. Further, additional unanticipated costs may be incurred in the integration of our businesses. Many of these factors are outside of our control, and any one of them could result in lower revenues, higher costs and diversion of management time and energy, which could materially impact our business, financial condition and results of operations.

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

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

- the possible failure of the third party to manufacture any such component of our products according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over ours or otherwise do not satisfactorily perform according to the terms of the agreements and/or purchase orders between us and them;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- supplier demands for significant cost increases;
- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- the possible breach by the third-party manufacturers of our agreements with them;

- the failure of third-party manufacturers to comply with applicable regulatory requirements;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- the possible failure of the third-party to manufacture any such components of our products according to our specifications; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with current Good Manufacturing Practice (cGMP) regulations applicable to our products. Third-party manufacturers may not be able, or fail, to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities.

In addition, we do not have complete control over the ability of our third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the FDA's Quality Regulation System (QSR) and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner. If the FDA or a comparable foreign regulatory authority withdraws any such approval they have already procured, we may need to find alternative manufacturing facilities, which would significantly impact our ability to market our products. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely harm our business and results of operations.

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

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

To ensure adequate inventory supply, we must forecast inventory needs and place orders with suppliers based on our estimates of future demand for our products. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to adequately manage our expansion efforts, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast customer acceptance of new product enhancements, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions.

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

Conversely, if we underestimate customer demand for our products, we may not be able to deliver sufficient products to meet our customers' requirements, which could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to

us, or at all, or suppliers or our third-party manufacturers may not be able to allocate sufficient resources to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

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

The manufacturing process of our products includes sourcing components from various third-party suppliers, assembly and testing. We must manufacture and assemble these systems in compliance with regulatory requirements and at an acceptable cost in order to achieve and maintain profitability. We have only a limited history of manufacturing and assembling our products and, as a result, we may have difficulty manufacturing and assembling 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 products on our expected timeline. As a result of this or any other delays, we may encounter difficulties in production of our products, including problems with quality control and assurance, component supply shortages or surpluses (including with respect to the ceramic and titanium we use in our products), increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements.

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

We have been growing rapidly in recent periods and have a relatively short history of operating as a commercial company. As of December 31, 2020, we had 416 employees. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

To achieve our revenue goals, we must successfully increase manufacturing output to meet expected customer demand. In the future, we may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate our revenue. Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth we will need to continue to improve our operational, compliance and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

In addition, as a public company, we need to support managerial, operational, financial and other resources to manage our operations, commercialize our products and continue our research and development activities. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth, and this growth may place significant strain on us as we grow. Successful growth will also be dependent upon our ability to implement appropriate financial and management controls. Due to our limited experience in managing a company with substantial 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.

We may require additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development activities, conducting clinical studies for our products, and building our dedicated direct sales

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

As of December 31, 2020, we had cash and cash equivalents of $241.2 million. On February 25, 2021, we announced the acquisition of Contura and its Bulkamid product. In consideration for the acquisition, we paid approximately $141.3 million in cash and issued 1,096,583 shares of our common stock. We may pay an additional $35 million in the event Bulkamid sales in any consecutive 12-month period exceed $50 million before December 31, 2024. In connection with the acquisition of Contura, on February 25, 2021, we entered into a Loan and Security Agreement (the Loan and Security Agreement) with Silicon Valley Bank, under which we obtained a loan in the principal amount of $75 million pursuant to a term loan advance (the Loan).

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

- the costs associated with manufacturing, selling, and marketing our products in the United States, as well as internationally, including the cost and timing of implementing our sales and marketing plan and expanding our manufacturing capabilities;
- our ability to retain and compensate the highly qualified personnel necessary to execute our plans;
- our ability to effectively market and sell, and achieve sufficient market acceptance and market share for, our products;
- the costs to maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights, including the Medtronic Litigation discussed under “Risks Related to Intellectual Property”;
- the emergence of competing technologies and other adverse market developments, and our need to enhance our products and/or develop new products to maintain market share in response to such competing technologies or market developments;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of license fees and sales of, or royalties on, or future improvements on our products, if any; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, incidental to being a public company.

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

We compete against other companies offering first-, second- and third-line therapies for the treatment of OAB and SUI, including Medtronic and Boston Scientific, respectively, some of which have longer operating

histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration and improved operating results.

We believe our r-SNM System and our Bulkamid product are designed to offer several needed improvements in the SNM and bulking agent markets for patients, physicians, and payors. However, the medical technology industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants.

We consider our primary competition to be other implantable SNM devices. On SNM, we face competition from major medical device companies worldwide, including Medtronic, the maker of InterStim II and InterStim Micro. InterStim II and InterStim Micro are currently the only other implantable SNM devices approved for commercial sale in the United States by the FDA. In August 2020, Medtronic received FDA approval for its Micro product, a rechargeable, implantable SNM device with a 15-year life in the body that treats the same patient population as Interstim II. This new offering could significantly impact the competitive landscape and our ability to capture and penetrate market share in the third-line therapy treatment market, and therefore could potentially have a material adverse effect on our business, financial condition and results of operation.

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

Bulkamid competes with bulking agents offered by Boston Scientific, Coloplast, and Laborie.

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

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

In addition to existing competitors, other larger and more established companies may acquire or in-license competitive products and could directly compete with us. These competitors may also try to compete with our products on price both directly, through rebates and promotional programs to high volume physicians and coupons to patients, and indirectly, through attractive product bundling with complementary products that offer convenience and an effectively lower price compared to the total price of purchasing each product separately. Larger competitors may also be able to offer greater customer loyalty benefits to encourage repeat use of their products and finance a sustained global advertising campaign to compete with commercialization efforts of our r-SNM System. Our competitors may seek to discredit our r-SNM System by challenging our short operating history or relatively limited number of scientific studies and publications. Additionally, certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we could. See "Risks Related to Intellectual Property—Litigation or other proceedings or third-party claims of intellectual property infringement against us, including the Medtronic Litigation, or any of our current or future licensors, including AMF, could require us to spend significant time and money and could prevent us from selling our r-SNM System, or affect our stock price." Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. As more companies develop new intellectual property in our market, there is the possibility of a competitor acquiring patents or other rights that may limit our ability to update our technologies and products which may impact demand for our r-SNM System.

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

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

We rely solely on Contura International A/S as a single source supplier to manufacture Bulkamid, and as such, any production or other problems with Contura International A/S could adversely affect us.

We depend solely upon Contura International for the manufacturing of Bulkamid, pursuant to the Manufacturing and Supply Agreement. Although alternative suppliers may exist, we are required to purchase Bulkamid exclusively from Contura International under the Manufacturing and Supply Agreement. Additionally, finding a replacement supplier with the capabilities required to manufacture Bulkamid could take a significant amount of our management's time and resources, and no such additional supplier may exist. Further, obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us.

In addition, our reliance on Contura International entails additional risks, including reliance on Contura International for regulatory compliance and quality assurance, the possible breach of the Manufacturing and Supply Agreement by Contura International, and the possible termination of the Manufacturing and Supply Agreement at a time that is costly or inconvenient for us. Our failure, or the failure of Contura International, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of Bulkamid. Our dependence on Contura Limited also subjects us to all of the risks related to Contura Limited's business, which are all generally beyond our control. Contura Limited's ability to perform its obligations under the Manufacturing

and Supply Agreement is dependent on Contura Limited's operational and financial health, which could be negatively impacted by several factors, including changes in the economic and political and legislative conditions.

Any termination or loss of significant rights under the License Agreement would materially and adversely affect our development and commercialization of our r-SNM System.

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

If AMF terminates the License Agreement under certain circumstances, we may be required to pay damages to AMF and AMF may have the right to terminate the license. In addition, if we do not have sufficient funds available to meet our payment obligations, AMF could 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.

If we are not successful in converting physicians and patients to our products, our business will not succeed.

Our success depends substantially on our r-SNM System, which was our sole product until we acquired the Bulkamid product on February 25, 2021. We expect our r-SNM System will drive the vast majority of our sales for the foreseeable future. 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 relied on the only other approved SNM therapy offered by Medtronic, InterStim II and its predecessor, InterStim I. As our r-SNM System is a new product in the SNM market, our primary strategy to penetrate the market and grow our revenue is to drive physician and patient awareness of the material benefits of our r-SNM System. Physicians and patients may choose not to adopt our r-SNM System for a number of reasons, including:

- familiarity with InterStim II or preference for Interstim Micro or any new device for the treatment of SNM that Medtronic could develop and commercialize in the future;
- lack of experience with our r-SNM System and with SNM as a treatment alternative;
- our inability to convince key opinion leaders to provide recommendations regarding our r-SNM System, or to convince physicians and patients that it is an attractive alternative to InterStim II, Interstim Micro and other third-line therapies such as BOTOX injections and PTNS;
- perceived or actual benefits of InterStim II or Interstim Micro;
- 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 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 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. We believe that educating healthcare providers and patients

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

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

It is important to our business and our long-term growth that we continue to enhance our 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 expanding the suite of product solutions available for SNM therapy, including a non-rechargeable SNM device that utilizes a primary-cell battery.

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

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

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

If the quality of our products do not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected.

In the course of conducting our business, we must adequately address quality issues that may arise with our products, including defects in third-party components included in our products. Although we have established internal procedures designed to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of our products do not meet the expectations of physicians or patients. For example, the anticipated battery life of our products 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 products do not meet the expectations of physicians or patients, then our brand and reputation with those physicians or patients, and our business, financial condition and results of operations, could be adversely affected.

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

Our estimates of the size and future growth in the market for SNM therapy and urethral bulking agents, including the number of people in the United States and Europe who suffer from symptoms of either bladder or bowel dysfunction and who are readily treatable with and eligible candidates for our 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 our therapy and our belief that the incidence of bladder and bowel dysfunction in the United States, Europe and worldwide is increasing. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for our therapy and our r-SNM System, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. The actual numbers of people with bladder or bowel dysfunction who are readily treatable with and eligible candidates for our therapy, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. As a result, our estimates of the size and future growth in the market for our products may prove to be incorrect. If the actual number of people with bladder or bowel dysfunction who would benefit from our products and the size and future growth in the market for our products is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business.

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

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

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

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

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

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

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

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

We 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, particularly our acquisition of Bulkamid, may adversely affect our business, operating results and financial condition. We have a robust and detailed integration plan for Bulkamid and believe that our extensive diligence and planning will result in a smooth integration, but we may face various challenges in effectively integrating this product into our company and we may not be able to overcome these challenges.

Potential complications from our products or future enhancements to our products may not be revealed by our clinical experience.

Based on our experience, complications from use of our r-SNM System may include infection, pain at site, lead migration or fracture, and the body's rejection of the implant. Complications of the use of Bulkamid include temporary pain, delayed urination, painful urination, and/or urinary tract infections. If unanticipated side-effects result from the use of our products, we could be subject to liability and our device would not be widely adopted. Long-term use may result in unanticipated complications, even after the device is removed. Additionally, while the INS 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.

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

In the United States, in order for physicians to use our products, we expect that the hospital facilities where these physicians treat patients will typically require us to enter into purchasing contracts. This process can be lengthy and time-consuming and require extensive negotiations and management time. In the European Union (EU) certain institutions may require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may decrease and our operating results may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

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

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

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

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. 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 products at prices necessary to support our current business strategies.

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

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

We have sales and operations both inside and outside the United States, including a limited sales and marketing organization outside the United States. Our international sales strategy is to increase our presence in Europe, Canada, and Australia, which have established and favorable reimbursement. With the purchase of Contura, we will greatly expand our international operations through its direct sales force and distribution agreements. International sales and operations are subject to a number of risks, including:

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

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

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

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

Many of our employees have become or will soon become vested in a meaningful amount of our common stock or common stock options. Our employees may be more likely to leave us if the shares they own or have the option to purchase have significantly appreciated in value relative to the original purchase price for the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Replacement of any employees who leave our company could involve significant time and costs and may

significantly delay or prevent the achievement of our business objectives, which could have an adverse effect on our business.

If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our products, our commercial success may be severely hindered, and in the event insurers require a prior authorization process, such process may not result in positive coverage determination for these patients.

In the United States, we derive most of our revenue from the sale of our products to hospitals and ASCs, which typically bill various third-party payors, including Medicare, Medicaid, private insurance companies, health maintenance organizations and other healthcare-related organizations. In addition, we expect that any portion of the costs and fees associated with our products that are not covered by these third-party payors, such as deductibles or co-payments, will be billed directly to the patient by the provider. Further, certain third-party payors may not cover our products and the related procedures because they may determine that our products and the related procedures are experimental or investigational. Customers that perform the procedure may be subject to reimbursement claim denials upon submission of the claim. Customers may also be subject to recovery of overpayments if a third-party payor makes payment for the claim and subsequently determines that the third-party payor's coding, billing or coverage policies were not followed. In addition, although most large insurers have established coverage policies in place to cover SNM and bulking agent therapy, certain commercial payors have a patient-by-patient prior authorization process that must be followed before they will provide reimbursement for SNM and bulking agent 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 and bulking agent 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 products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

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 products 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 products are 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 products. We intend to work with payors to obtain coverage and reimbursement approval in countries and regions where it makes economic sense to do so, however, we may not obtain such coverage, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business internationally.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future enhancements to our products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products could result in patient injury or death. The medical technology industry has historically been subject to

extensive litigation over product liability claims, and we may face product liability suits. We may be subject to product liability claims if our products cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our products and develop enhancements to our products;
- decreased demand for our products;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical study participants;
- substantial monetary awards to patients or other claimants; or
- loss of sales.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations.

Although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

We bear the risk of warranty claims on our products.

We bear the risk of warranty claims on our products. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or third-party manufacturers in the event of a successful warranty claim against us by a customer or and any recovery from any such supplier or third-party manufacturer could be inadequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers or third-party manufacturers expires, which could result in costs to us.

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 products, 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.

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

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

If our facilities are damaged or become inoperable, we will be unable to continue to research and develop our products and, as a result, there will be an adverse effect on our business until we are able to secure a new facility and rebuild our inventory.

We perform substantially all of our research and development and back office activity and maintain a substantial portion of our finished goods inventory for our r-SNM System 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.

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

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. FCPA, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, EU, and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the FCPA and other federal statutes and regulations, including those established by the OFAC. In addition, the U.K. Bribery Act of 2010 (the Bribery Act) prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that "fails to prevent bribery" by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented "adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including

cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations.

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

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

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.

A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries and all 50 states within the United States. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by significantly decreasing and delaying the number of procedures performed using our r-SNM System, and we expect the pandemic to continue to negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our r-SNM System has decreased significantly as healthcare organizations in the United States and globally, including in Europe and Canada have prioritized the treatment of patients with COVID-19 or have altered their operations to prepare for and respond to the pandemic. For example, in the United States, governmental authorities have recommended, and in certain cases required, or healthcare providers have decided that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. We believe the COVID-19 pandemic has also negatively impacted the number of OAB, FI and UR diagnoses and patients screened for eligibility for our r-SNM system as hospitals and ambulatory surgery centers focus on COVID-19 and as patients postpone healthcare visits and treatments. Specifically, substantially all of the procedures using our r-SNM System were postponed or cancelled from middle of March 2020 through May 2020, but order flow began a gradual recovery in May 2020 and continued to improve in the second half of 2020. Many areas in the United States have since restarted procedures

with our r-SNM System, but the situation is evolving rapidly and remains uncertain due to recent increases in COVID-19 cases and related hospitalizations. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will continue to significantly reduce our revenue and negatively impact our business, financial condition and results of operations while the pandemic continues. Further, once the pandemic subsides, we anticipate there will be a substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers relating to a variety of medical conditions, and as a result, patients seeking procedures performed using our r-SNM System, may have to navigate limited provider capacity. We believe this limited provider, hospital and ambulatory surgery center capacity could have a significant adverse effect on our business, financial condition and results of operations following the end of the pandemic. Additionally, even after it is deemed advisable to resume conducting elective procedures, some patients may elect not to undergo procedures or delay scheduling procedures to avoid traveling to healthcare facilities due to safety concerns.

Numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Since March 19, 2020, the governor of California, where our headquarters are located, has issued several orders related to COVID-19, including “stay at home” orders limiting non-essential activities, travel and business operations for a period of time. Such orders or restrictions have resulted in reduced operations at our headquarters, modified operations at our manufacturing facility, work slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby significantly and negatively impacting our operations. Other disruptions or potential disruptions include restrictions on the ability of our sales representatives, clinical specialists and other personnel to travel and access customers for training and case support; inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; delays in actions of regulatory bodies; delays in operations at insurance agencies, which may impact timelines for the issuance of insurance coverage policies and local coverage determinations; delays in clinical trials; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; delays in growing or reductions in our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives or salary and compensation reductions; restrictions in our ability to ship our products to customers; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; increase in bad debts due to an adverse impact of the pandemic on our clients’ cash flows and resulting decrease in collectability of our account receivables; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers’ capacity to manufacture and sell our products. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could have a material adverse effect on our long-term business as hospitals curtail and reduce capital and overall spending. In addition, the current economic downturn is resulting in significant job losses and reductions in disposable income and if patients are unable to obtain or maintain health insurance policies, this may significantly impact their ability to pay for the procedures utilizing our r-SNM System, further negatively impacting our business, financial condition and results of operations. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described herein, including those relating to incurring future operating losses, dependence of the r-SNM System, successful commercialization, supply chain and distribution channels.

Risks Related to Government Regulation

Our operations are subject to extensive government regulation and oversight both in the United States and internationally, and our failure to comply with applicable requirements could harm our business.

We are subject to extensive, complex, costly and evolving regulation in the United States, the United Kingdom, the EU, Canada and other countries, including by the FDA and its foreign counterparts. With respect to medical devices, the FDA and foreign regulatory agencies regulate, among other things, design, development and manufacturing, testing, labeling, content and language of instructions for use and storage, clinical studies, product safety, establishment registration and device listing, marketing, sales and distribution, premarket clearance and approval, record keeping procedures, advertising and promotion, recalls and field safety corrective actions, postmarket surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury, postmarket approval studies, and product import and export.

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

We are also subject to the periodic scheduled or unscheduled inspection of our facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in costly remediation efforts, requirements that we complete government mandated clinical studies or government enforcement actions. The manufacturers that we work with are similarly subject to periodic scheduled or unscheduled inspections of their facilities. Adverse findings during such inspections may impact our inventory and cause disruptions in product sales.

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

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

Modifications to products that are approved through a PMA application generally require FDA approval. In addition, a PMA generally requires the performance of one or more clinical studies. Despite the time, effort and cost, a device or modification may not be approved or cleared by the FDA. Any modifications to our products that were not previously approved may require us to submit an additional PMA or PMA supplement and obtain FDA approval prior to implementing the change. If the FDA requires us to go through a lengthier, more rigorous examination, make modifications to the device, or generate additional data to submit to the FDA, future product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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

- inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that the device is safe or effective for its intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of clinical studies or the interpretation of data from pre-clinical studies or clinical studies;

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

The FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may impact our ability to modify our products or introduce future products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain approvals once obtained.

In order to sell our products in member countries of the European Economic Area (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) (the AIMD Directive). If any future product candidates are also considered to qualify as an active implantable medical device, or AIMD, under the AIMD Directive, it too will need to comply with the essential requirements it sets out. Alternatively, if a future product candidate is not considered an AIMD under the AIMD Directive, it will still be required to comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). The Medical Devices Regulations (Regulation 2017/745) are also now in force, as further discussed below.

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

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

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

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

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

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

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

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about approved medical devices, such as our products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or other similar regulatory authorities as reflected in the product's approved labeling. Physicians could use our products on their patients in a manner that is inconsistent with the approved label. We will train our marketing personnel and sales representatives to not promote our products for uses outside of FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those that may be approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

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

In addition, physicians may misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to an increased risk of product liability claims. If our products are misused or used with improper techniques or are determined to cause or contribute to patient harm, we may become subject to costly litigation by our customers or patients. Product liability claims could divert management's attention from the commercialization of our products, 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 products.

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

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

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

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

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

- we may be required to submit an IDE application to FDA, which must become effective prior to commencing human clinical studies, and the FDA may reject our IDE application and notify us that we may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies;
- regulators and/or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical study at a prospective or specific trial site for various reasons, including safety signals or noncompliance with regulatory requirements;
- we may not reach agreements with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;

- the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- our third-party manufacturers, including those conducting clinical studies on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical study protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- the cost of clinical studies may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical study sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers or suppliers of materials for our clinical studies, the materials necessary to conduct clinical studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our products or other product candidates may have undesirable side effects or other unexpected characteristics.

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

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

clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned. Our failure to adequately demonstrate the safety and effectiveness of any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, limit our ability to commercialize the product.

Failure to comply with postmarketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw our products from the market.

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

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

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

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

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

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

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

If treatment guidelines for OAB, SUI, FI or UR change or the standard of care evolves, we may need to redesign and seek a new marketing authorization from the FDA for our products.

If treatment guidelines for OAB, SUI, FI or UR change or the standard of care evolves, we may need to redesign our products, or any future product, and seek new approvals from the FDA. PMA approvals from the FDA are based on current treatment guidelines at the time of the approvals. If treatment guidelines change so that different treatments become desirable, the clinical utility of our products could be diminished and our business could be adversely affected.

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

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

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

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we may determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement

could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our products, a number of potentially negative consequences could result, including:

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

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

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

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

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

Legislative or regulatory reforms in the United States or Europe may make it more difficult and costly for us to obtain regulatory clearances or approvals for modifications to our products, or to manufacture, market or distribute our products.

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

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.

The effects of the withdrawal of the United Kingdom from the EU (Brexit) will depend on any agreements the United Kingdom makes to retain access to EU markets. 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 and implementation 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 $102,522 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 (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 (CHIP) to report annually to the DHHS Centers for Medicare and Medicaid Services (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 (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 products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and responding to any such challenge or investigation would be costly and divert the attention of our management. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that

apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations.

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

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

The EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, which are often more restrictive than those in the United States and which restrict transfers of personal data to the United States unless certain requirements are met. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. 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 (the GDPR), which came into effect on May 25, 2018, as well as current challenges to these mechanisms in the European courts.

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

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

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

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

- 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 products, 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 products, 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 products, which in turn could impact our ability to successfully commercialize our products 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 (DRC) or any of its adjoining countries, or covered countries, then we must conduct diligence on the source and chain of custody of those conflict minerals to determine if they originated in one of the covered countries and, if so, whether they financed or benefited armed groups in the covered

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

Risks Related to Intellectual Property

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

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

Third parties may assert that we, or any of our current or future licensors, including AMF, are employing their proprietary technology without authorization. For example, on November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (collectively, the Medtronic Affiliates) filed an initial complaint against us in the United States District Court for the Central District of California, Case No. 8:19-cv-2115, and amended the complaint on November 26, 2019. We refer to this matter as the Medtronic Litigation. The complaint asserts that our r-SNM System infringes U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324 and 9,821,112 held by the Medtronic Affiliates, and the amended complaint further includes the additional patents 8,738,148; 8,457,758; and 7,774,069 (collectively, the Medtronic Patents). The Medtronic Litigation requests customary remedies for patent infringement, including (i) a judgment that we have infringed and are infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) a permanent injunction preventing us from infringing the Medtronic Patents, (iv) attorneys' fees, and (v) costs and expenses. We believe the allegations are without merit and are vigorously defending ourselves against them. Given the early stage of the Medtronic Litigation, we are unable to predict the likelihood of success of the claims of the Medtronic Affiliates against us or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and require us to dedicate significant financial resources and management resources to our defense.

An adverse ruling against us could materially and adversely affect our business, financial position, results of operations or cash flows and could also result in reputational harm. Even if we are successful in defending against these claims, the Medtronic Litigation could result in significant costs, delays in future product developments, reputational harm or other collateral consequences.

On March 16, 2020, we filed seven petitions before the United States Patent and Trademark Office (USPTO) requesting inter partes review (IPR) to contest the validity of each of the Medtronic patents that Medtronic has alleged are being infringed by us. In September 2020, the USPTO decided that it will accept or "institute" the IPR process for six of the seven patents, finding that we had demonstrated a reasonable likelihood that at least one, if not all, of the claims of these six patents are invalid. We are currently in the IPR discovery process. The USPTO will usually render a decision on the validity of contested patents within twelve months of instituting the review. We filed a motion to stay the proceedings before the United States District Court for the Central District of California pending resolution of the IPR process. Our motion was granted by the court on May 8, 2020.

Defense of any of the above claims, including the Medtronic Litigation, would require us to dedicate substantial time and resources, which time and resources could otherwise be used by us toward the maintenance of our own intellectual property and the commercialization of our products, or by any of our current or future licensors for operational upkeep and manufacturing of our products.

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

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

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

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

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

Our intellectual property coverage includes protection provided by patents and other intellectual property licensed through the License Agreement with AMF. We rely on AMF to maintain the patents and otherwise protect the intellectual property we license from them. 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 products and several issued patents and patent applications were licensed from AMF in 2013 pursuant to the License Agreement. As of December 31, 2020, we own 32 issued U.S. patents and 89 issued foreign patents, and 19 pending U.S. patent applications and 41 pending foreign patent applications. We also license from AMF 30 issued U.S. patents and three pending U.S. patent applications, as well as 65 issued foreign patents and 10 pending foreign patent applications. Issued patents owned or used by us will expire between 2021 and 2040.

Our patents may not have, and any of our pending patent applications that mature into issued patents may not include, claims with a scope sufficient to adequately protect our products, or any additional features we develop for our products or any new products. Other parties may have developed technologies that may be related to or competitive with our products, and, may have filed, or may file, patent applications, and, may have received, or may receive patents, that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent, or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to commercialize our products.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, circumvent or design around our patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. In addition, third parties may create new products or methods that achieve similar results without infringing upon patents we own. If these developments were to occur, it could have an adverse effect on our sales or market position. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. In addition, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in some, or any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some, or all, of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or, if a court found that valid, enforceable patents held by third parties covered our products, our competitive position could be harmed, or, we could be required to incur significant expenses to enforce or defend our rights.

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

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

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

We are reliant on the ability of AMF, as licensor of certain intellectual property contained in our products, and may be reliant on, future licensors to maintain their intellectual property and protect their intellectual property against misappropriation, infringement or other violation. In some instances, we may not have primary control over AMF's, or our other future licensors', patent prosecution activities. With respect to licensed patents that were issued to our licensors, or patents that may issue on patent applications, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. As a licensee, we are reliant on AMF to defend any third-party claims or consent to our defending them on their behalf. Our licensors may not

defend or prosecute such actions as vigorously or in the manner that we would have if entitled to do so, and we will be subject to any judgment or settlement resulting from such actions and our business could be adversely affected.

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

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

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. If we face similar challenges with respect to material intellectual property matters, this could make it difficult for us to stop infringement of our foreign patents or our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Litigation may be necessary in the future to enforce our intellectual property rights or protect our trade secrets or other proprietary information, which is an expensive and time-consuming process with uncertain outcomes. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from the commercialization of our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may, in the future, make claims challenging the inventorship or ownership of our intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be

precluded from using certain intellectual property or we may lose our rights in that intellectual property. Either outcome could harm our business and competitive position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information, including trade secrets or other proprietary information, of former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Any litigation or the threat thereof may adversely affect our ability to hire employees and we may lose valuable intellectual property rights if we fail in defending any such claims. A loss of key personnel or their work product could diminish or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

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

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

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

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.

We are a party to the License Agreement with AMF and we may be a party to future license agreements. One or more of our licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license. If successful, this could result in our loss of the right to use the licensed intellectual property, which could adversely affect our ability to commercialize our products, as well as harm our competitive business position and our business prospects. In particular, the License Agreement imposes various development, royalty, insurance and other obligations on us. If we fail to comply with these obligations or otherwise materially breach the License Agreement, AMF may have the right to terminate the License Agreement, in which event we would not be able to market our products. In addition, any claims asserted against us by AMF may be costly and time-consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business.

Risks Related to Our Common Stock

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

Our stock price may be volatile. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, some of which are beyond our control, including:

- the impact of worldwide pandemics on voluntary surgical procedures;
- unanticipated safety concerns related to the use of our products;
- FDA or other U.S. or foreign regulatory or legal actions or changes affecting us or our industry;
- intellectual property, product liability or other litigation against us, our third-party manufacturers or other parties on which we rely or litigation against our general industry;
- any termination or loss of rights under the License Agreement;
- any voluntary or regulatory mandated product recalls;
- adverse developments concerning our manufacturers or suppliers or any future strategic partnerships;
- introductions and announcements of new technologies by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- announcements of regulatory approval or disapproval of our products or for any future enhancements to our products;
- adverse results from or delays in clinical studies of our products;
- our ability to successfully integrate acquired operations into our ongoing business;
- variations in our financial results or those of companies that are perceived to be similar to us;
- success or failure of competitive products or therapies in the SNM market;
- changes in the structure of healthcare payment of our products;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the medical technology industry and issuance of securities analysts' reports or recommendations;
- quarterly variations in our results of operations or those of our competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- the public's reaction to our earnings releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- sales of substantial amounts of our stock by directors, officers or significant stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions, including the size and growth, if any, of the market;
- news reports relating to trends, concerns and other issues in the market or industry;
- operating and stock performance of other companies that investors deem comparable to us and overall performance of the equity markets;
- additions or departures of key personnel;

- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- the results of any future legal proceedings; and
- other factors described in this "Risk Factors" section.

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

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

Based on the beneficial ownership of our common stock as of December 31, 2020, our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, controlled approximately 25% of our outstanding common stock. As a result, these stockholders, if they act together, could exercise significant control over 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.

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

We have incurred and will continue to incur significant costs associated with corporate governance requirements that are applicable to us as a public company, including rules and regulations of the SEC, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Securities Exchange Act of 1934 (the Exchange Act), as well as the listing requirements of Nasdaq. These rules and regulations are expected to significantly increase our accounting, legal and financial compliance costs and make some activities more time-consuming. We also expect these rules and regulations to make it more expensive for us to maintain our directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition and results of operations.

We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in us, and, as a result, the value of our common stock.

To comply with the requirements of being a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. Further, the Sarbanes-Oxley Act also requires that our internal control over financial reporting be attested to by our independent registered public accounting firm.

If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. The process of designing and implementing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control

over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on Nasdaq.

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

We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Anti-takeover provisions in our certificate of incorporation and bylaws, as well as under Delaware law, could discourage a takeover.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove members of our board of directors. Because our board of directors is responsible for appointing the members of our

management team, these provisions could in turn affect any attempt by our stockholders to replace or remove current members of our management team. These include the following provisions that:

- permit our board of directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, without stockholder approval, which could be used to dilute the ownership of a hostile bidder significantly;
- provide that 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 (DGCL) which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This provision could have the effect of delaying or preventing a change in control of our company, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws, any action asserting a claim that is governed by the internal affairs doctrine and the resolution of any complaint asserting a cause of action arising under the Securities Act, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein and the claim not being one which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or for which the Court of Chancery does not have subject matter jurisdiction.

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

In November 2017, we entered into a seven-year operating lease for approximately 25,548 square feet of office space beginning on August 1, 2018, and expiring on August 31, 2025. In June 2019, the lease was amended to extend the expiration date to October 31, 2027. We have a renewal option to extend the term of the lease for a period of five years beyond the initial term.

In June 2019, we entered into an eight-year operating lease for approximately 32,621 square feet of office space beginning on January 15, 2020 and expiring on January 31, 2028. We use these premises as our new principal executive offices and for general office space. We intend to utilize our other currently-leased spaces through the lease expiration dates to conduct the training of our sales team and for manufacturing purposes.

In August 2020, we entered into a 38-month operating lease for approximately 5,693 square feet of warehouse space beginning on October 15, 2020 and expiring on December 31, 2023. The Company uses these premises for general warehouse space.

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

Item 3. Legal Proceedings.

On November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (collectively, the Medtronic Affiliates) filed an initial complaint against us in the United States District Court for the Central District of California, Case No. 8:19-cv-2115, and amended the complaint on November 26, 2019. We refer to this matter as the Medtronic Litigation. The complaint asserts that our r-SNM System infringes U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324 and 9,821,112 held by the Medtronic Affiliates, and the amended complaint further includes the additional patents 8,738,148; 8,457,758; and 7,774,069

(collectively, the Medtronic Patents). The Medtronic Litigation requests customary remedies for patent infringement, including (i) a judgment that we have infringed and are infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) a permanent injunction preventing us from infringing the Medtronic Patents, (iv) attorneys' fees, and (v) costs and expenses. We believe the allegations are without merit and are vigorously defending ourselves against them. Given the early stage of the Medtronic Litigation, we are unable to predict the likelihood of success of the claims of the Medtronic Affiliates against us or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and require us to dedicate significant financial resources and management resources to our defense. An adverse ruling against us could materially and adversely affect our business, financial position, results of operations or cash flows and could also result in reputational harm. Even if we are successful in defending against these claims, the Medtronic Litigation could result in significant costs, delays in future product developments, reputational harm or other collateral consequences.

On March 16, 2020, we filed seven petitions before the United States Patent and Trademark Office (USPTO) requesting inter partes review (IPR) to contest the validity of each of the Medtronic patents that Medtronic has alleged are being infringed by us. In September 2020, the USPTO decided that it will accept or "institute" the IPR process for six of the seven patents, finding that we had demonstrated a reasonable likelihood that at least one, if not all, of the claims of these six patents are invalid. We are currently in the IPR discovery process. The USPTO will usually render a decision on the validity of contested patents within twelve months of instituting the review. We filed a motion to stay the proceedings before the United States District Court for the Central District of California pending resolution of the IPR process. Our motion was granted by the court on May 8, 2020.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market for Common Stock

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

Holders of Record

At February 25, 2021, there were approximately 310 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid cash dividends on our common stock. Because we currently intend to retain all future earnings to finance future growth, we do not anticipate paying any cash dividends in the near future. In addition, pursuant to the Loan Agreement with Silicon Valley Bank, we are prohibited from paying cash dividends without the prior written consent of Silicon Valley Bank.

Recent Sales of Unregistered Securities

Except as previously disclosed in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, we had no sales of unregistered equity securities during fiscal year 2020.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Performance Graph

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

$100 investment in stock or index	October 31, 2018	December 31, 2018	December 31, 2019	December 31, 2020
Axonics Modulation Technologies, Inc. (AXNX)	$ 100.00	$ 100.87	$ 184.98	$ 326.37
S&P 500 Index	$ 100.00	$ 92.44	$ 119.14	$ 137.63
S&P 500 Health Care Equipment Index	$ 100.00	$ 90.96	$ 111.33	$ 147.89

Item 6. Selected Financial Data.

Not applicable.

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

Overview

We are a global medical technology company that develops and commercializes products to treat urinary and fecal dysfunction, including: (i) an implantable SNM to treat UUI and UUF, together referred to as OAB, as well as FI, and non-obstructive UR; and (ii) a urethral bulking agent to treat female SUI.

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

We estimate the global SNM market is now approximately $650 million to $700 million and believe it is a growing market that is currently about one to three percent penetrated. Until we entered the market, it was serviced by Medtronic as a single participant.

We believe our proprietary r-SNM System, the first rechargeable SNM system marketed worldwide, offers significant advantages, and is well positioned to capture market share and penetrate and grow this attractive market. Our r-SNM System is designed to last approximately 15 years in the human body, is only 5cc in volume, offers broad MRI access, ease of use, intuitive programmers, and the longest recharging interval among rechargeable SNM systems.

We have marketing approvals in Europe, Canada, and Australia for all relevant clinical indications and initiated limited commercial efforts in England, the Netherlands and Canada in late 2018. Revenue in 2020 from international operations in the Netherlands, England, Canada, Switzerland, Norway and Germany, was approximately $4.0 million.

Our initial PMA application for our r-SNM System for the treatment of FI was approved by the FDA on September 6, 2019, and our PMA application for our r-SNM System for the treatment of OAB and UR was approved by the FDA on November 13, 2019.

We are primarily focused on commercializing our products in the United States, which accounts for the vast majority of SNM sales worldwide. We have established a significant commercial infrastructure, with over 220 sales personnel and clinical specialists and we continue to make significant investments to build our commercial organization to market and support our products. When making hiring decisions for these roles, we prioritize individuals with strong sales backgrounds and experience in SNM therapy and other neurostimulation applications, and who also have existing relationships with urologists and urogynecologists.

Revenue in 2020 from accounts located across the United States was approximately $107.5 million.

In January 2020, the FDA approved an enhanced, second-generation programmer for our r-SNM System under a PMA supplement. The new programmer features, among other things, a predictive programming algorithm that translates intra-operative responses and suggests how to program the patient for optimum therapy, thereby reducing the need to adjust post-implant therapy.

In April 2020, the FDA approved a second-generation INS for our r-SNM System under a PMA supplement. The second-generation INS extends the recharge interval for patients to only once a month for about one hour and for some patients, up to once every two months. The second-generation INS began shipping to customers in the U.S. during the third quarter of 2020.

In June 2020, the FDA approved a new wireless patient remote control with SmartMRI™ technology for our r-SNM System under a PMA supplement. The new remote control simplifies the process by which patients can receive a full-body magnetic resonance imaging (MRI). An MRI technician can perform a simple check using a patient’s remote control immediately prior to an MRI, avoiding the need for the patient to visit their implanting physician’s office or involving our personnel.

In July 2020, the FDA approved 3T full-body MRI conditional labeling for our r-SNM System under a PMA supplement. With this incremental approval, our r-SNM System is MRI compatible for both 1.5T and 3T full-body scans.

In September 2020, Health Canada approved a second-generation rechargeable INS for our r-SNM System, which the Company began shipping upon approval.

In February 2021, the FDA approved a third-generation INS for our r-SNM System under a PMA supplement. The third-generation INS upgrades the embedded software in the INS and the functionality of the patient remote control. These modifications give patients the ability to make broader stimulation parameter

adjustments at home, including selecting a second therapy program that was set post-operatively based on interoperative findings.

Our ability to generate revenue and become profitable will depend on our ability to continue to successfully commercialize our r-SNM System and any product enhancements we may advance in the future. We expect to derive future revenue by increasing patient and physician awareness of our r-SNM System. 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 sufficient revenue in the future, our business, results of operations, financial condition, cash flows, and future prospects would be materially and adversely affected.

We also intend to continue to make investments in research and development efforts to develop improvements and enhancements to our r-SNM System.

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

Prior to obtaining FDA approval, we 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. We expect to spend a significant amount of our resources on sales and marketing activities as we commercialize and market our r-SNM System in the United States.

We incurred net losses of $54.9 million, $79.9 million, and $32.5 million for the years ended December 31, 2020, 2019, and 2018, respectively, and had an accumulated deficit of $234.5 million as of December 31, 2020 compared to $179.6 million at December 31, 2019. As of December 31, 2020, we had available cash and cash equivalents of approximately $241.2 million, current liabilities of approximately $45.7 million, and long-term liabilities of approximately $9.2 million.

Prior to our initial public offering (IPO), we financed our operations primarily through preferred stock financings and amounts borrowed under a Loan and Security Agreement, dated February 6, 2018, between us and Silicon Valley Bank (the Loan Agreement). Through our IPO in November 2018, an offering completed in November 2019 and an offering completed in May 2020, we received aggregate gross proceeds of approximately $405.1 million. We have invested heavily in product development and continuous improvement to our r-SNM System. We have also made significant investments in clinical studies to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions. Because of these and other factors, we expect to continue to incur net losses for the next few years and we may require additional funding, which may include future equity and debt financings. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material and adverse effect on our business, financial condition, and results of operations.

Initial Public Offering

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

November 2019 Follow-On Offering

On November 22, 2019, we completed a follow-on offering by issuing 5,345,000 shares of common stock, at an offering price of $22.00 per share, inclusive of 750,000 shares of our common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The gross proceeds to us from this follow-on offering were $117.6 million and the net proceeds were approximately $110.4 million, after deducting underwriting discounts, commissions and offering expenses payable by us.

May 2020 Follow-On Offering

On May 12, 2020, we completed a follow-on offering by issuing 4,600,000 shares of common stock, at an offering price of $32.50 per share, inclusive of 600,000 shares of our common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The gross proceeds to us from this follow-on offering were $149.5 million and the net proceeds were approximately $140.5 million, after deducting underwriting discounts, commissions and offering expenses payable by us.

Impact of COVID-19

The COVID-19 pandemic negatively impacted our sales, primarily in the second quarter of 2020, by significantly decreasing and delaying the number of procedures performed using our r-SNM System, and we expect that the pandemic could negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our r-SNM System decreased significantly as healthcare organizations in the United States and globally, including in Europe and Canada, have prioritized the treatment of patients with COVID-19 or have altered their operations to prepare for and respond to the pandemic. Specifically, substantially all of the procedures using our r-SNM System were postponed or cancelled from middle of March 2020 through May 2020, but order flow began a gradual recovery in May 2020 and continued to improve in the second half of 2020.

To protect the health of our employees, their families, and our communities, we have restricted access to our offices to personnel who must perform critical activities that must be completed on-site, limited the number of such personnel that can be present at our facilities at any one time, requested that many of our employees work remotely, and implemented strict travel restrictions. These restrictions and precautionary measures have not adversely affected our operations. The full extent of COVID-19's effect on our operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and additional protective measures implemented by the governmental authorities, all of which are uncertain and difficult to predict considering the rapidly evolving landscape. However, if the pandemic continues to evolve into a long-term severe worldwide health crisis, there could be a material adverse effect on our business, results of operations, financial condition, and cash flows.

AMF License Agreement

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

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale

anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) the Minimum Royalty, payable quarterly. The Minimum Royalty automatically increases each year, subject to a maximum amount of $200,000 per year. During the years ended December 31, 2020, 2019, and 2018, we have recorded royalties of $4.4 million, $0.6 million, and $0.1 million, respectively. We have 60 days to pay AMF the royalty amount due under the License Agreement, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

Components of Our Results of Operations

Net Revenue

Revenue in 2020 from U.S. operations was $107.5 million.

Revenue in 2020 from international operations in the Netherlands, England, Canada, Switzerland, Norway and Germany, was approximately $4.0 million.

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. 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. Cost of goods sold also include other expenses such as scrap and inventory obsolescence. We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our 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. 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 and foreign currency exchange rates. Our gross margin may increase over the long term to the extent our production volumes increase and we receive discounts on the costs charged by our contract manufacturers, thereby reducing our per unit costs. Additionally, our gross margin may fluctuate from quarter to quarter due to seasonality.

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, royalty expense, travel expenses, and equipment-related expenses and other miscellaneous office and facilities expenses related to research and development programs. Research and development costs are expensed as incurred. We expect to continue incurring research and development expenses in the future as we develop next generation versions of our r-SNM System 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, 2020, 2019, and 2018 (in thousands):

	Years Ended December 31,		
	2020	2019	2018
Personnel related	$ 12,176	$ 11,917	$ 8,452
Clinical development	501	1,401	4,572
Contract fabrication and manufacturing	6,159	642	3,572
Contract R&D and consulting	8,810	4,847	1,713
Other R&D expenses	1,524	1,374	1,093
Total R&D expenses	$ 29,170	$ 20,181	$ 19,402

General and Administrative Expenses

General and administrative expenses consist primarily of employee compensation, including stock-based compensation, and spending related to finance, information technology, human resource functions, consulting, legal, and professional service fees. Other general and administrative expenses include director and officer insurance premiums, investor relations costs, office-related expenses, facilities and equipment rentals, bad debt expense, 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 legal expenses associated with our patent infringement litigation with Medtronic. These expenses will further increase as we no longer qualify as an "emerging growth company" under the Jumpstart Our Business Startups (JOBS) Act, which requires us to comply with certain reporting requirements effective December 31, 2020. 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 employee compensation, including stock-based compensation, trade shows, booth exhibition costs, and the related travel for these events. Other sales and marketing expenses include consulting and advisory fees. We expect sales and marketing expenses to continue to increase in absolute dollars as we expand our commercial infrastructure to both drive and support our expected growth in revenue. However, we expect sales and marketing expenses to decrease as a percentage of revenue in the long term 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.

Income Tax Expense

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

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table shows our results of operations for the years ended December 31, 2020 and 2019 (in thousands, except percentages):

	Years Ended December 31,		Period to Period Change
	2020	2019	
Net revenue	$ 111,535	$ 13,820	$ 97,715
Cost of goods sold	44,444	6,490	37,954
Gross profit	67,091	7,330	59,761
Gross Margin	*60.2 %*	*53.0 %*	
Operating Expenses			
Research and development	29,170	20,181	8,989
General and administrative	25,551	19,076	6,475
Sales and marketing	66,130	48,672	17,458
Total operating expenses	120,851	87,929	32,922
Loss from operations	(53,760)	(80,599)	26,839
Other Income (Expense)			
Interest income	761	2,974	(2,213)
Loss on disposal of property and equipment	(41)	—	(41)
Interest and other expense	(1,874)	(2,309)	435
Other income (expense), net	(1,154)	665	(1,819)
Loss before income tax expense	(54,914)	(79,934)	25,020
Income tax expense	1	1	—
Net loss	(54,915)	(79,935)	25,020
Foreign currency translation adjustment	(3)	(12)	9
Comprehensive loss	$ (54,918)	$ (79,947)	$ 25,029

Net Revenue

Net revenue was $111.5 million in fiscal year 2020 and was derived from the sale of our r-SNM Systems to customers in the United States, Europe and Canada. Net revenue was $13.8 million in fiscal year 2019 and was derived from the sale of our r-SNM Systems to customers in the United States, Europe and Canada. The increase in net revenue is primarily due to the commercial launch in the United States in the fourth quarter of 2019, partially offset by a decrease in sales in Europe and Canada as related to the COVID-19 pandemic.

Cost of Goods Sold and Gross Margin

We incurred $44.4 million of cost of goods sold in fiscal year 2020, compared to $6.5 million in fiscal year 2019. Gross margin was 60.2% in fiscal year 2020, compared to 53.0% gross margin in fiscal year 2019. The increase in gross margin is primarily due to higher sales volume as well as the commercial launch in the United States in the fourth quarter of 2019, which has higher average sales prices.

Research and Development Expenses

Research and development expenses increased $9.0 million, or 44.5%, to $29.2 million in fiscal year 2020, compared to $20.2 million in fiscal year 2019. The increase in research and development expenses was primarily attributable to an increase of $5.5 million in contract fabrication and manufacturing costs related to product development projects and an increase of $4.0 million in contract research and development and consulting expenses,

partially offset by $0.9 million decrease in clinical development costs to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions.

General and Administrative Expenses

General and administrative expenses increased $6.5 million, or 33.9%, to $25.6 million in fiscal year 2020, compared to $19.1 million in fiscal year 2019, primarily as a result of an increase of $2.4 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, an increase of $1.9 million in legal and consulting costs, and an increase of $1.0 million in rent expense.

Sales and Marketing Expenses

Sales and marketing expenses increased $17.5 million, or 35.9%, to $66.1 million in fiscal year 2020, compared to $48.7 million in fiscal year 2019. The increase in sales and marketing expenses was primarily due to an increase of $19.8 million related to personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, partially offset by a decrease of $2.3 million in travel expenses.

Other Income (Expense), Net

Other expense, net was $1.2 million in fiscal year 2020, consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank, partially offset by interest income earned on cash equivalents. Other income, net was $0.7 million in fiscal year 2019, consisting primarily of interest income earned on cash equivalents and short-term investments, partially offset by interest expense incurred related to the Loan Agreement with Silicon Valley Bank

Income Tax Expense

Income tax expense was minimal in fiscal year 2020 and 2019.

Liquidity and Capital Resources

We only began full-scale commercialization of our r-SNM System in late 2019. We have expended significant resources on research and development activities, growing our operations organization and building and training our sales organization.

We incurred net losses of $54.9 million, $79.9 million, and $32.5 million for the years ended December 31, 2020, 2019, and 2018, respectively, and had an accumulated deficit of $234.5 million as of December 31, 2020 compared to $179.6 million at December 31, 2019. We expect to continue to spend a significant amount of our existing resources on sales and marketing activities as we continue to commercialize and market our products in the United States and internationally.

As of December 31, 2020, we had cash and cash equivalents of $241.2 million compared to cash, cash equivalents and short-term investments of $183.7 million at December 31, 2019. We expect that our cash, cash equivalents and short-term investments on hand will be sufficient to fund our operations through at least the next 12 months. We fund our operations through a combination of proceeds from public offerings of our common stock, cash receipts from sales of our r-SNM System and proceeds from our Loan Agreement with Silicon Valley Bank. As of December 31, 2020, we had $21.5 million in outstanding borrowings, as discussed below under “Indebtedness,” which were repaid in January 2021.

In connection with the acquisition of Contura, on February 25, 2021, we entered into the Loan and Security Agreement with Silicon Valley Bank, as the administrative agent and collateral agent for the lenders, under which we obtained a loan in the principal amount of $75 million pursuant to the Loan. The Loan under the Loan and Security Agreement matures on February 1, 2024 (the Maturity Date), unless earlier accelerated upon an event of default. The Loan bears interest at a floating per annum rate equal to the greater of (a) 9.00% and (b) 5.75% above the current prime rate, with only interest due and payable monthly until September 1, 2022, at which time interest and principal will be due and payable monthly in equal monthly payments. The Loan and Security Agreement also sets out that the Loan is subject to a final payment fee equal to 6.00% of the aggregate principal amount of the Loan.

We may prepay amounts outstanding under the Loan and Security Agreement at any time with 5 days prior written notice to Silicon Valley Bank. In the event that we elect to prepay the Loan prior to the Maturity Date, we are required to pay a fee in the amount of (a) 2.00% of the outstanding principal balance if such prepayment occurs

prior to February 25, 2022 or (b) 1.00% of the outstanding principal balance if such prepayment occurs on or after February 25, 2022.

The Loan and Security Agreement contains customary covenants that include, among others, covenants that limit our and our subsidiaries' ability to dispose of assets, conduct mergers or acquisitions, incur indebtedness, incur certain liens, pay dividends or make distributions on our capital stock, make certain investments, and enter into certain affiliate transactions, in each case subject to customary exceptions for a credit facility of this size and type.

The Loan and Security Agreement contains customary events of default that include, among others, non-payment defaults, covenant defaults, a default in the event a material adverse change occurs, defaults in the event our assets are attached or we are enjoined from doing business, bankruptcy and insolvency defaults, cross-defaults to certain other material indebtedness, material judgment defaults, and inaccuracy of representations and warranties. The occurrence of an event of default could result in an increase to the applicable interest rate of 5.00%, acceleration of and present occurrence of the Maturity Date, and the consequent obligation for us to repay in full in cash all amounts outstanding under the Loan and Security Agreement, and a right by the lenders to exercise all remedies available under the Loan and Security Agreement and related agreements, including the right to dispose of the collateral as permitted under applicable law.

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

Cash Flows

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

	Years Ended December 31,		
	2020	2019	2018
Net cash provided by (used in)			
Operating activities	$ (83,742)	$ (83,454)	$ (31,370)
Investing activities	9,654	45,287	(60,050)
Financing activities	144,190	110,955	165,342
Effect of exchange rate changes on cash and cash equivalents	(3)	(12)	(14)
Net increase in cash and cash equivalents	$ 70,099	$ 72,776	$ 73,908

Net cash used in operating activities

Net cash used in operating activities was $83.7 million in fiscal year 2020 and consisted primarily of a net loss of $54.9 million, a decrease from changes in net operating assets of $47.0 million, partially offset by non-cash charges of $18.2 million. Net operating assets consisted primarily of inventory to support the commercial launch of our r-SNM System in the United States. Non-cash charges consisted primarily of stock-based compensation.

Net cash used in operating activities was $83.5 million in fiscal year 2019 and consisted primarily of a net loss of $79.9 million, a decrease in net operating assets of $14.4 million, partially offset by non-cash charges of $10.9 million. Net operating assets consisted primarily of inventory to support the commercial launch of our r-SNM System in the United States. Non-cash charges consisted primarily of stock-based compensation.

Net cash used in operating activities was $31.4 million in fiscal year 2018 and consisted primarily of a net loss of $32.5 million, a decrease in net operating assets of $2.9 million, partially offset by non-cash charges of $4.0 million. Net operating assets consisted primarily of inventory to support the planned launch of our commercial

operations. Non-cash charges consisted primarily of forgiveness of receivables for stock subscriptions, depreciation and amortization, and stock-based compensation.

Net cash provided by (used in) investing activities

Net cash provided by investing activities was $9.7 million in fiscal year 2020 and consisted primarily of sales and maturities of short-term investments, partially offset by purchases of property and equipment. Not included is the approximately $141.3 million in cash paid and 1,096,583 shares of our common stock issued from the acquisition of Contura and its Bulkamid product.

Net cash provided by investing activities was $45.3 million in fiscal year 2019 and consisted primarily of sales and maturities of short-term investments, partially offset by purchases of short-term investments.

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

Net cash provided by financing activities

Net cash provided by financing activities was $144.2 million in fiscal year 2020 and consisted primarily of $140.5 million in net proceeds received in the follow-on offering. Not included is the $75 million in proceeds from the Loan and Security Agreement.

Net cash provided by financing activities was $111.0 million in fiscal year 2019 and consisted primarily of $110.4 million in net proceeds received in the follow-on offering.

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

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.

Contractual Obligations

Our principal contractual obligations consist of payments due under the Loan Agreement, including interest and principal payments and the final payment. The following table sets out, as of December 31, 2020, our contractual obligations due by period (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations[1]	$ 13,141	$ 1,945	$ 3,708	$ 3,626	$ 3,862
Purchase Obligations[2]	30,116	30,116	—	—	—
Other Long-Term Liabilities[3]	2,525	150	375	400	1,600
Long-term Debt[4]	21,797	21,797	—	—	—
Total	$ 67,579	$ 54,008	$ 4,083	$ 4,026	$ 5,462

(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 October 31, 2027. In addition, we maintain offices at 15326 Alton Parkway, Irvine, California 92618, where we lease approximately 32,621 square feet of office space under a lease that terminates on January 31, 2028, and at 7575 Irvine Center Drive, Suite 200, Irvine, California 92618, where we lease approximately 12,215 square feet of space, and where we conduct the training of our sales team, under a lease that terminates on July 31, 2022.

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

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

(4) Includes interest payments at the prime rate plus 1.75%, prepayment fees, and the minimum final payment, consisting of a 7.5% premium principal amount paid off under the Loan Agreement, all of which were repaid in full in January 2021. Fees or payments under the Loan and Security Agreement are not included.

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, the Loan and Security 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 (GAAP) requires our management to make estimates and judgments that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and such differences may be material to our consolidated financial statements.

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

Revenue Recognition

Revenue recognized during the years ended December 31, 2020, 2019, and 2018 relates entirely to the sale of our r-SNM System.

We have revenue arrangements that consist of a single performance obligation. We recognize revenue at the point in time when it transfers control of promised goods to its customers. Revenue is measured as the amount of consideration it expects to receive in exchange for transferring goods. The amount of revenue that is recognized is based on the transaction price, which represents the invoiced amount and includes estimates of variable consideration such as discounts, where applicable. We do not offer rights of return or price protection. The amount of variable consideration included in the transaction price may be constrained and is included only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Payment terms, typically less than three months, are offered to our customers and do not include a significant financing component. We extend credit to our customers based upon an evaluation of the customer’s financial condition and credit history and generally require no collateral. We do not have any contract balances related to product sales. We also do not have significant contract acquisition costs related to product sales.

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

Allowance for Doubtful Accounts

We make estimates of the collectability of accounts receivable. Upon adoption of ASU 2016-13, we did not recognize an adjustment to the beginning balance of retained earnings as the impact from adoption was not material. Our estimate of future losses is made by management based upon historical bad debts, customer receivable balances, age of customer receivable balances, customers’ financial conditions and reasonable forecasted economic trends. Despite our efforts to minimize credit risk exposure, clients could be adversely affected if future economic and industry trends, including those related to COVID-19, change in such a manner as to negatively impact their cash

flows. The full effects of COVID-19 on our clients are highly uncertain and cannot be predicted. As a result, our future collection experience can differ significantly from historical collection trends. If our clients experience a negative impact on their cash flows, it could have a material adverse effect on our results of operations and financial condition.

Fair Value of Financial Instruments

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

- Level 1: Inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs are quoted prices for similar assets and liabilities in active markets or quoted prices for identical or similar instruments in markets that are not active and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
- Level 3: Inputs are unobservable inputs based on our assumptions and valuation techniques used to measure assets and liabilities at fair value. The inputs require significant management judgment or estimation.

Our assessment of the significance of an input to the fair value measurement requires judgment, which may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels. The carrying amounts reported in the consolidated financial statements approximate the fair value for cash and cash equivalents, accounts receivable, accounts payables, and accrued expenses, due to their short-term nature. The carrying amount of our term loan, which is described below, approximates fair value, considering the interest rates are based on the prime interest rate.

Investment Securities

We classify our investment securities as available-for-sale. Those investments in debt securities with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments in debt securities with maturities greater than 12 months at the date of purchase are considered long-term investments. Our investment securities classified as available-for-sale are recorded at fair value based on the fair value hierarchy (Level 1 and Level 2 inputs in the fair value hierarchy), and consists primarily of commercial paper, corporate notes and U.S. government and agency securities. Unrealized gains or losses, deemed temporary in nature, are reported as other comprehensive income within the consolidated statement of comprehensive income (loss).

Foreign Currency Translation

The functional currencies of the Company’s subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Costs and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders’ equity 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).

Inventory, Net

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

We capitalize inventory produced for commercial sale. We capitalize manufacturing costs as inventory following both the receipt of regulatory approval from regulatory bodies and our intent to commercialize. Costs associated with developmental products prior to satisfying our inventory capitalization criteria are charged to research and development expense as incurred.

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

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

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

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

Intangible Asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The additional field-of-use was provided in exchange for 50,000 shares of Series A preferred stock, the fair value of which was $1.0 million in 2013. The intangible asset was recorded at its fair value of $1.0 million at the date contributed. In connection with our IPO, such shares of Series A preferred stock were converted into common stock. Amortization of this asset is recorded over the shorter of the patent or legal life on a straight-line basis. The weighted-average amortization period is 8.71 years. We will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date.

Impairment of Long-Lived Assets

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

Leases

In accordance with ASU No. 2016-02, “Leases (Topic 842)”, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components. Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. We have elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only. Topic 842 allows for the use of judgment in determining whether the assumed lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. We apply the bright line thresholds referenced in Topic 842 to assist in evaluating leases for appropriate classification. The aforementioned bright lines are applied consistently to our entire portfolio of leases.

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

Research and Development

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

Advertising Expense

The Company expenses advertising costs as they are incurred.

Income Taxes

We account for income taxes using the asset and liability method to compute the difference between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. We have deferred tax assets. The realization of these deferred tax assets is dependent upon our ability to generate sufficient taxable income in future years. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. We evaluate the recoverability of the deferred tax assets annually, and maintain a full valuation allowance on our deferred tax assets. 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 are subject to transfer pricing and other tax regulations designed to ensure that appropriate levels of income are reported as earned by our U.S. and foreign entities and are taxed accordingly. In the normal course of business, we are audited by federal, state and foreign tax authorities, and subject to inquiries from those tax authorities regarding the amount of taxes due. These inquiries may relate to the timing and amount of deductions and the allocation of income among various tax jurisdictions. Our policy is to recognize interest and penalties related to unrecognized tax benefits, if any, in income tax expense.

Stock-Based Compensation

We measure the cost of employee and non-employee services in exchange for an award of equity instruments based on the grant-date fair value of the award and recognize compensation cost over the requisite service period (typically the vesting period), generally four years. Forfeitures are estimated at the time of the grant and revised in subsequent periods to reflect differences between the estimates and the number of shares that actually become exercisable. We use the Black-Scholes option pricing model to determine the fair value of stock options (as of the date of grant) that have service conditions for vesting. Stock options and restricted shares awards vest based on service conditions, typically over four years.

We also grant shares of performance-based restricted stock units that typically vest after one year only if we have also achieved certain performance objectives as defined and approved by our board of directors. The fair value of performance awards are determined based on the Company's stock price at the date of grant and expensed over the performance period based on the probability of achieving the performance objectives. In addition, we also grant market-based restricted stock units that have combined market conditions and service conditions for vesting, for which we use the Monte Carlo valuation model to value equity awards (as of the date of grant).

Recent Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosure 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 and cash equivalents of $241.2 million as of December 31, 2020, which came from IPO and follow-on offerings of our common 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 and Security 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 products do not increase as much as or more than these increased costs.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Axonics 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") as of December 31, 2020 and 2019, the related consolidated statements of comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2020, the consolidated statement of mezzanine equity for the year ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated March 1, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Income Taxes

As described in Notes 1 and 8 to the consolidated financial statements, the Company's accounting for income taxes requires the recognition of deferred tax assets, liabilities, and valuation reserves for the expected future tax consequences of events that have been included in the consolidated financial statements. The Company operates in multiple countries, which requires specialized knowledge of the income tax laws in various federal, state and foreign jurisdictions. In addition, the Company has significant net operating loss carryforwards that may be limited under Section 382 of the Internal Revenue Code.

We identified the accounting for certain components of income taxes, including transfer pricing and the realizability of net operating loss carryforwards as a critical audit matter. Our determination results from the specialized skill and knowledge required to properly account for income taxes, including the development of complex assumptions used in the transfer pricing study and related determinations and the significant amount of management judgement necessary to evaluate the realizability of net operating loss carryforwards. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters, including the extent of specialized skill or knowledge needed.

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

- Utilizing personnel with specialized skill and knowledge in transfer pricing to assist in evaluating the reasonableness of the Company's assumptions, inputs and methods used in the transfer pricing studies related to inter-company transactions.
- Utilizing personnel with specialized skill and knowledge in federal, state and foreign jurisdiction income taxes to assist in evaluating the reasonableness of the assumptions used in the assessment of the realizability of the net operating loss carryforwards considering Section 382 of the Internal Revenue Code.

/s/ BDO USA, LLP

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

Costa Mesa, California
March 1, 2021

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

	December 31,	
	2020	2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 241,181	$ 171,082
Short-term investments	—	12,592
Accounts receivable, net of allowance for doubtful accounts of $465 and $75 at December 31, 2020 and 2019, respectively	18,270	7,879
Inventory, net	63,060	15,659
Prepaid expenses and other current assets	5,435	4,468
Total current assets	327,946	211,680
Property and equipment, net	6,328	3,047
Intangible asset, net	196	311
Other assets	7,736	4,784
Total assets	$ 342,206	$ 219,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 10,660	$ 5,882
Accrued liabilities	6,684	2,174
Accrued compensation and benefits	5,948	3,375
Operating lease liability, current portion	1,280	602
Debt, net of unamortized debt issuance costs, current portion	21,110	—
Total current liabilities	45,682	12,033
Operating lease liability, net of current portion	9,154	4,450
Debt, net of unamortized debt issuance costs, net of current portion	—	20,336
Total liabilities	54,836	36,819
Stockholders' Equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, par value $0.0001 per share, 50,000,000 shares authorized at December 31, 2020 and 2019; 39,931,030 and 34,110,995 shares issued and outstanding at December 31, 2020 and 2019, respectively	4	3
Additional paid-in capital	522,296	363,012
Accumulated deficit	(234,499)	(179,584)
Accumulated other comprehensive loss	(431)	(428)
Total stockholders' equity	287,370	183,003
Total liabilities and stockholders' equity	$ 342,206	$ 219,822

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2020	**2019**	**2018**
Net revenue	$ 111,535	$ 13,820	$ 707
Cost of goods sold	44,444	6,490	356
Gross profit	67,091	7,330	351
Operating Expenses			
Research and development	29,170	20,181	19,402
General and administrative	25,551	19,076	9,362
Sales and marketing	66,130	48,672	3,724
Total operating expenses	120,851	87,929	32,488
Loss from operations	(53,760)	(80,599)	(32,137)
Other Income (Expense)			
Interest income	761	2,974	998
Loss on disposal of property and equipment	(41)	—	—
Interest and other expense	(1,874)	(2,309)	(1,343)
Other income (expense), net	(1,154)	665	(345)
Loss before income tax expense	(54,914)	(79,934)	(32,482)
Income tax expense	1	1	1
Net loss	(54,915)	(79,935)	(32,483)
Foreign currency translation adjustment	(3)	(12)	(14)
Comprehensive loss	$ (54,918)	$ (79,947)	$ (32,497)
Net loss per share, basic and diluted (see Note 1)	$ (1.48)	$ (2.80)	$ (4.64)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	36,981,335	28,567,302	6,997,777

See accompanying notes to consolidated financial statements.

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

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

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Stock Subscriptions Receivable	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount					
Balance at December 31, 2017	2,776,583	$ —	$ 2,900	$ (1,753)	$ (67,166)	$ (402)	$ (66,421)
Issuance of common stock for employee stock option exercises for promissory notes	48,720	—	71	(71)	—	—	—
Issuance of common stock for employee stock option exercises for cash	7,120	—	9	—	—	—	9
Warrants for common stock	—	—	986	—	—	—	986
Repurchase of common stock	(38,786)	—	(473)	—	—	—	(473)
Forgiveness of stock subscriptions receivable	—	—	—	1,824	—	—	1,824
Conversion of preferred stock to common stock	15,813,297	2	113,190	—	—	—	113,192
Initial public offering - issuance of 9,200,000 shares at $15.00 per share, less closing costs of $11,951	9,200,000	1	126,048	—	—	—	126,049
Stock-based compensation	—	—	606	—	—	—	606
Foreign currency translation adjustment	—	—	—	—	—	(14)	(14)
Net loss	—	—	—	—	(32,483)	—	(32,483)
Balance at December 31, 2018	27,806,934	3	243,337	—	(99,649)	(416)	143,275
Issuance of common stock for employee stock option exercises for cash	281,744	—	506	—	—	—	506
Restricted Shares Award (RSA) issuances and forfeitures for terminations, net and stock-based compensation	613,717	—	7,655	—	—	—	7,655
Issuance of common stock for vesting of Restricted Stock Units (RSU) and stock-based compensation	—	—	1,065	—	—	—	1,065
Follow-on offering - issuance of 5,345,000 shares at $22.00 per share, less closing costs of $7,141	5,345,000	—	110,449	—	—	—	110,449
Issuance of common stock for warrant exercise	63,600	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	(12)	(12)
Net loss	—	—	—	—	(79,935)	—	(79,935)
Balance at December 31, 2019	34,110,995	3	363,012	—	(179,584)	(428)	183,003
Issuance of common stock for employee stock option exercises for cash	767,792	—	3,703	—	—	—	3,703
RSA issuances and forfeitures for terminations, net and stock-based compensation	405,907	—	11,792	—	—	—	11,792
Issuance of common stock for vesting of RSU and stock-based compensation	46,336	—	3,303	—	—	—	3,303
Follow-on offering - issuance of 4,600,000 shares at $32.50 per share, less closing costs of $9,013	4,600,000	1	140,486	—	—	—	140,487
Foreign currency translation adjustment	—	—	—	—	—	(3)	(3)
Net loss	—	—	—	—	(54,915)	—	(54,915)
Balance at December 31, 2020	39,931,030	$ 4	$ 522,296	$ —	$ (234,499)	$ (431)	$ 287,370

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2020	**2019**	**2018**
Cash Flows from Operating Activities			
Net loss	$ (54,915)	$ (79,935)	$ (32,483)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	1,741	1,191	946
Loss on disposal of property and equipment	41	—	—
Stock-based compensation	15,095	8,720	606
Amortization of debt issuance costs	774	873	338
Provision for doubtful accounts	390	75	—
Forgiveness of stock subscriptions receivable	—	—	1,824
Change in fair value of warrants	—	—	254
Other items	165	—	—
Changes in operating assets and liabilities			
Accounts receivable	(10,781)	(7,527)	(427)
Inventory	(47,353)	(11,986)	(2,255)
Prepaid expenses and other current assets	(863)	(752)	(3,009)
Other assets	(90)	(299)	65
Accounts payable	4,778	2,446	1,820
Accrued liabilities	4,193	1,155	846
Accrued compensation and benefits	2,573	2,711	214
Lease liability	510	(126)	(109)
Net cash used in operating activities	(83,742)	(83,454)	(31,370)
Cash Flows from Investing Activities			
Purchases of property and equipment	(2,938)	(1,339)	(1,228)
Purchases of short-term investments	—	(36,404)	(78,122)
Proceeds from sales and maturities of short-term investments	12,592	83,030	19,300
Net cash provided by (used in) investing activities	9,654	45,287	(60,050)
Cash Flows from Financing Activities			
Payment of debt issuance costs	—	—	(142)
Proceeds from debt	—	—	20,000
Proceeds from exercise of stock options	3,703	506	9
Proceeds from issuance of common stock upon follow-on public offering	149,500	117,590	—
Payment of common stock issuance costs upon follow-on public offering	(9,013)	(7,141)	—
Proceeds from issuance of common stock upon initial public offering	—	—	138,000
Payment of common stock issuance costs upon initial public offering	—	—	(11,951)
Proceeds from issuance of preferred stock and noncontrolling interest	—	—	20,098
Payment of preferred stock issuance costs	—	—	(199)
Repurchase of common stock	—	—	(473)
Net cash provided by financing activities	144,190	110,955	165,342
Effect of exchange rate changes on cash and cash equivalents	(3)	(12)	(14)
Net increase in cash and cash equivalents	70,099	72,776	73,908
Cash and cash equivalents, beginning of year	171,082	98,306	24,398
Cash and cash equivalents, end of year	$ 241,181	$ 171,082	$ 98,306
Supplemental Disclosure of Cash Flow Information			
Cash paid for interest	$ 1,102	$ 1,436	$ 751
Cash paid for taxes	$ 1	$ 1	$ 1
Noncash Investing and Financing Activities			
Common stock issuance on stock option exercises for promissory notes	$ —	$ —	$ 71
Warrants issued as debt issuance costs	$ —	$ —	$ 733
Accrued loan fees as debt issuance costs	$ —	$ —	$ 1,500
Forgiveness of stock subscriptions receivable	$ —	$ —	$ 1,824

See accompanying notes to consolidated financial statements.

AXONICS MODULATION TECHNOLOGIES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Nature of Operations

Axonics Modulation Technologies, Inc. (the Company), formerly American Restorative Medicine, Inc., was incorporated in the state of Delaware on March 2, 2012. The Company had no operations until October 1, 2013, when the license agreement between Alfred E. Mann Foundation for Scientific Research (AMF) and the Company (the License Agreement) was entered into. The Company is a medical technology company that has developed and is commercializing innovative and minimally invasive implantable neurostimulation systems. The Company has designed and developed the rechargeable sacral neuromodulation (SNM) system (r-SNM System), which delivers mild electrical pulses to the targeted sacral nerve in order to restore normal communication to and from the brain to reduce the symptoms of overactive bladder (OAB), urinary retention (UR) and fecal incontinence (FI). The r-SNM System is protected by intellectual property based on Company-generated innovations and patents and other intellectual property licensed from AMF. The Company has marketing approvals in the United States, Europe, Canada, and Australia for all relevant clinical indications. The premarket approval (PMA) application for the r-SNM System for the treatment of FI was approved by the U.S. Food and Drug Administration (FDA) on September 6, 2019, and the PMA application for the r-SNM System for the treatment of OAB and UR was approved by the FDA on November 13, 2019. Accordingly, the Company began U.S. commercialization of its r-SNM System in the fourth quarter of 2019. Prior to the fourth quarter of 2019, the Company derived revenue only from its international operations in select markets including England, the Netherlands and Canada, and its activities have consisted primarily of developing the r-SNM System, conducting its RELAX-OAB post-market clinical follow-up study in Europe, its ARTISAN-SNM pivotal clinical study in the United States and hiring and training its U.S. commercial team in preparation for the launch of the r-SNM System in the United States.

Initial Public Offering

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

November 2019 Follow-On Offering

On November 22, 2019, the Company completed a follow-on offering by issuing 5,345,000 shares of common stock, at an offering price of $22.00 per share, inclusive of 750,000 shares of the Company's common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The net proceeds to the Company were approximately $110.4 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company.

May 2020 Follow-On Offering

On May 12, 2020, the Company completed a follow-on offering by issuing 4,600,000 shares of common stock, at an offering price of $32.50 per share, inclusive of 600,000 shares of the Company's common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The net proceeds to the Company were approximately $140.5 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company, its wholly-owned subsidiaries, Axonics Europe, S.A.S., Axonics Modulation Technologies U.K. Limited and Axonics Modulation Technologies Australia Pty Ltd. Intercompany accounts and transactions have been eliminated in consolidation.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). Certain prior year reported amounts have been reclassified to conform with the 2020 presentation.

Stock Split and Charter Amendment

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

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

COVID-19

The recent COVID-19 outbreak, and the resulting restrictions intended to slow the spread of COVID-19, including stay-at-home orders, business shutdowns and other restrictions, has adversely affected the Company's business in several ways. The primary impact on the Company's business was the cancellation or delay of elective procedures in certain areas to allow health care facilities to prioritize the treatment of COVID-19 patients during the initial stages of the pandemic or because patients are avoiding health care facilities that they feel are unsafe. These developments materially reduced the number of procedures using the Company's r-SNM System. If governmental authorities recommend that it is deemed advisable for health care facilities to not perform outpatient elective procedures as was the case in late March and April of 2020, the Company expects it would materially harm the Company's revenues and potentially increase the Company's operating loss. These challenges will likely continue for the duration of the pandemic and could reduce our revenue and negatively impact our business, financial condition and results of operations while the pandemic continues. If these delays in procedures occur in the future, the Company may have to scale back its business, including reducing headcount, which could have a negative impact on the Company's long-term operations. The Company could also experience other negative impacts of the COVID-19 outbreak such as the lack of availability of the Company's key personnel, temporary closures of the Company's office or the facilities of the Company's business partners, customers, third party service providers or other vendors, and the interruption of the Company's supply chain, distribution channels, liquidity and capital or financial markets.

Any disruption and volatility in the global capital markets as a result of the pandemic may increase the Company's cost of capital and adversely affect the Company's ability to access financing when and on terms that the Company desires. In addition, a recession resulting from the spread of COVID-19 could materially affect the Company's business, especially if a recession results in higher unemployment causing potential patients to not have access to health insurance.

The ultimate extent to which the COVID-19 pandemic and its repercussions impact the Company's business will depend on future developments, which are highly uncertain. However, the foregoing and other continued disruptions to the Company's business as a result of COVID-19 could result in a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires the Company's management to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses, and related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience

and on various other assumptions that it believes to be reasonable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and such differences may be material to the consolidated financial statements.

Revenue Recognition

Revenue recognized during the years ended December 31, 2020, 2019, and 2018 relates entirely to the sale of our r-SNM System.

The Company has revenue arrangements that consist of a single performance obligation. The Company recognizes revenue at the point in time when it transfers control of promised goods to its customers. Revenue is measured as the amount of consideration it expects to receive in exchange for transferring goods. The amount of revenue that is recognized is based on the transaction price, which represents the invoiced amount and includes estimates of variable consideration such as discounts, where applicable. The Company does not offer rights of return or price protection. The amount of variable consideration included in the transaction price may be constrained and is included only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Payment terms, typically less than three months, are offered to the Company's customers and do not include a significant financing component. The Company extends credit to its customers based upon an evaluation of the customer's financial condition and credit history and generally requires no collateral. The Company does not have any contract balances related to product sales. The Company also does not have significant contract acquisition costs related to product sales.

In accordance with Company policy and based on the Company's historical experience, the allowance for product returns was $0.3 million and zero at December 31, 2020 and 2019, respectively. Damaged or defective products are replaced at no charge under the Company's standard warranty. For the years ended December 31, 2020, 2019, and 2018, the replacement costs were $0.1 million, minimal, and zero, respectively.

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

The following table provides additional information pertaining to net revenue disaggregated by geographic market for the years ended December 31, 2020, 2019, and 2018 (in thousands):

	Years Ended December 31,		
	2020	**2019**	**2018**
United States	$ 107,542	$ 8,376	$ —
International markets	3,993	5,444	707
Total net revenue	$ 111,535	$ 13,820	$ 707

Allowance for Doubtful Accounts

The Company makes estimates of the collectability of accounts receivable. Upon adoption of ASU 2016-13, the Company did not recognize an adjustment to the beginning balance of retained earnings as the impact from adoption was not material. The Company's estimate of future losses is made by management based upon historical bad debts, customer receivable balances, age of customer receivable balances, customers' financial conditions and reasonable forecasted economic trends. Despite the Company's efforts to minimize credit risk exposure, clients could be adversely affected if future economic and industry trends, including those related to COVID-19, change in such a manner as to negatively impact their cash flows. The full effects of COVID-19 on the Company's clients are highly uncertain and cannot be predicted. As a result, the Company's future collection experience can differ significantly from historical collection trends. If the Company's clients experience a negative impact on their cash flows, it could have a material adverse effect on the Company's results of operations and financial condition.

The following table summarizes the changes in our allowance for doubtful accounts (in thousands):

	Years Ended December 31,		
	2020	2019	2018
Balance at beginning of period	$ 75	$ —	$
Bad debt expense	390	75	
Balance at end of period	$ 465	$ 75	$

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 as the Company's policy is to place its cash and cash equivalents in highly-rated financial institutions.

Fair Value of Financial Instruments

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

- Level 1: Inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs are quoted prices for similar assets and liabilities in active markets or quoted prices for identical or similar instruments in markets that are not active and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
- Level 3: Inputs are unobservable inputs based on the Company's assumptions and valuation techniques used to measure assets and liabilities at fair value. The inputs require significant management judgment or estimation. The Company's assessment of the significance of an input to the fair value measurement requires judgment, which may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels. The carrying amounts reported in the consolidated financial statements approximate the fair value for cash and cash equivalents, accounts receivable, accounts payables, and accrued expenses, due to their short-term nature. The carrying amount of the Company's term loan, which is described below, approximates fair value, considering the interest rates are based on the prime interest rate.

Investment Securities

The Company classifies its investment securities as available-for-sale. Those investments in debt securities with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments in debt securities with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based on the fair value hierarchy (Level 1 and Level 2 inputs in the fair value hierarchy), and consists primarily of commercial paper, corporate notes and U.S. government and agency securities. Unrealized gains or losses, deemed temporary in nature, are reported as other comprehensive income within the consolidated statement of comprehensive income (loss). There were no unrealized gains or losses during the years ended December 31, 2020, 2019, and 2018.

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

included in net income (loss) and are derived using the specific identification method for determining the cost of securities sold.

The Company had no outstanding investment securities as of December 31, 2020. The following table presents the fair value hierarchy for those assets measured at fair value on a recurring basis as of December 31, 2019 (in thousands):

	Fair Value Measurements at December 31, 2019			
Assets:	**Level 1**	**Level 2**	**Level 3**	**Total**
Commercial paper	$ —	$ 7,195	$ —	$ 7,195
Corporate notes	2,018	—	—	2,018
U.S. government and agency securities	3,379	—	—	3,379
	$ 5,397	$ 7,195	$ —	$ 12,592

Foreign Currency Translation

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Costs and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' equity 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, 2020 and 2019, all foreign currency translation gains (losses) have been unrealized and included in accumulated other comprehensive loss. Accumulated other comprehensive loss consists entirely of losses or gains from translation of foreign subsidiaries at December 31, 2020 and 2019. Foreign currency transaction gains and losses are included in results of operations and have not been significant for the periods presented.

Inventory, Net

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

The Company capitalizes inventory produced for commercial sale. The Company capitalizes manufacturing costs as inventory following both the receipt of regulatory approval from regulatory bodies and the Company's intent to commercialize. Costs associated with developmental products prior to satisfying the Company's inventory capitalization criteria are charged to research and development 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 certain 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 36 months and, based on sales forecasts, the Company expects to realize the carrying value of the product inventory. In the future, reduced demand, quality issues, or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

The determination of whether 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.

As of December 31, 2020, the Company had $42.1 million, $3.5 million, and $17.5 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, on hand net of minimal reserves. As of December 31, 2019, the Company had $7.0 million, $1.5 million and $7.2 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, on hand net of reserves of $0.1 million.

Customer and Vendor Concentration

As of December 31, 2020 and 2019, there were no customers who accounted for over 10% of the Company's consolidated accounts receivable. As of December 31, 2020 and 2019, there was one and no vendor, respectively, who accounted for over 10% of the Company's consolidated accounts payable.

Property and Equipment

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

Intangible Asset

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

In accordance with ASU No. 2016-02, “Leases (Topic 842)”, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components. Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only. Topic 842 allows for the use of judgment in determining whether the assumed lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. The Company applies the bright line thresholds referenced in Topic 842 to assist in evaluating leases for appropriate classification. The aforementioned bright lines are applied consistently to the Company’s entire portfolio of leases.

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, which is the rate for a fully collateralized amortizing loan with the same maturity as the lease term, 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.

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.

Advertising Expense

The Company expenses advertising costs as they are incurred. During the years ended December 31, 2020, 2019, and 2018, advertising expense totaled $2.9 million, $2.6 million and $1.1 million, respectively, and are recorded within the sales and marketing expenses in its consolidated statements of comprehensive loss.

Income Taxes

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

Stock-Based Compensation

The Company measures the cost of employee and non-employee services in exchange for an award of equity instruments based on the grant-date fair value of the award and recognizes compensation cost over the requisite service period (typically the vesting period), generally four years. Forfeitures are estimated at the time of the grant and revised in subsequent periods to reflect differences between the estimates and the number of shares that actually become exercisable. The Company uses the Black-Scholes option pricing model to determine the fair value of stock options (as of the date of grant) that have service conditions for vesting. Stock options and restricted shares awards vest based on service conditions, typically over four years.

The Company also grants shares of performance-based restricted stock units that typically vest after one year only if the Company has also achieved certain performance objectives as defined and approved by the Company's board of directors. The fair value of performance awards are determined based on the Company's stock price at the date of grant and expensed over the performance period based on the probability of achieving the performance objectives. In addition, the Company also grants market-based restricted stock units that have combined market conditions and service conditions for vesting, for which the Company uses the Monte Carlo valuation model to value equity awards (as of the date of grant).

Net Loss per Share of Common Stock

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

For the years ended December 31, 2020, 2019, and 2018, there were 2,300,982, 1,737,430, and 9,192,127 potentially dilutive weighted-average shares, respectively, that were not included in the computation of diluted weighted-average shares of common stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-15, "Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract," which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This guidance is effective for annual periods beginning after December 15, 2019, which was the Company's first quarter of fiscal year 2020. The adoption of this guidance did not have an impact on the Company's consolidated financial statements or related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement," which modifies the disclosure requirements on fair value measurements and is intended to improve the effectiveness of disclosures, including the consideration of costs and benefits. This guidance is effective for annual periods beginning after December 15, 2019, which was the Company's first quarter of fiscal year 2020, with early adoption permitted. The adoption of this guidance did not have an impact on the Company's consolidated financial statements or related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments," which updates the methodology used to measure current expected credit losses (CECL). This guidance applies to financial assets measured at amortized cost, including loans, held-to-maturity debt securities, net investments in leases, and trade accounts receivable as well as certain off-balance sheet credit exposures, such as loan commitments. This guidance replaces the current incurred loss impairment methodology with a methodology to reflect CECL and requires consideration of a broader range of

reasonable and supportable information to explain credit loss estimates. The guidance must be adopted using a modified retrospective transition method through a cumulative-effect adjustment to retained earnings (deficit) in the period of adoption. This guidance is effective for the Company as of January 1, 2020. The adoption of this guidance did not have an impact on the Company's consolidated financial statements or related disclosures

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, "Income Taxes—Simplifying the Accounting for Income Taxes," which simplifies the accounting for income taxes by clarifying and amending existing guidance related to the recognition of franchise tax, the evaluation of a step-up in the tax basis of goodwill and the effects of enacted changes in tax laws or rates in the effective tax rate computation, among other clarifications. This guidance is effective for annual periods beginning after December 15, 2020, which is the Company's first quarter of fiscal year 2021, with early adoption permitted. The adoption of this guidance is not expected to have an impact on the Company's consolidated financial statements or related disclosures.

Note 2. Property and Equipment

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

	December 31,	
	2020	**2019**
Research and development equipment	$ 1,205	$ 1,086
Computer hardware and software	2,286	1,418
Tools and molds	1,404	1,303
Leasehold improvements	3,759	1,500
Furniture and fixtures	1,360	624
Construction in progress	129	176
	10,143	6,107
Less: accumulated depreciation and amortization	(3,815)	(3,060)
	$ 6,328	$ 3,047

Depreciation and amortization expense of property and equipment was $1.6 million, $1.1 million, and $0.8 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Note 3. Intangible Asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The intangible asset was recorded at its fair value of $1.0 million at the date contributed in 2013, which is the gross carrying amount of the intangible asset at December 31, 2020 and 2019. Accumulated amortization of the intangible asset is $0.8 million and $0.7 million at December 31, 2020 and 2019, respectively. The Company recorded expense for the amortization of intangible assets of $0.1 million during the years ended December 31, 2020, 2019, and 2018. The estimated future amortization expense as of December 31, 2020, is as follows (in thousands):

2021	$ 115
2022	81
	$ 196

Note 4. Commitments and Contingencies

Operating Leases

In August 2014, the Company entered into a five-year operating lease for approximately 12,215 square feet of office space beginning on November 1, 2014, and expiring on October 31, 2019. In June 2019, the lease was amended to extend the expiration date to October 31, 2020 and in September 2020, the lease was amended to extend

the expiration date to July 31, 2022. Upon the execution of the amendments, which were deemed to be a lease modification, the Company reassessed the lease liability using the discount rate at the modification date and recorded ROU assets for the same amount. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term.

In November 2017, the Company entered into a seven-year operating lease for approximately 25,548 square feet of office space beginning on August 1, 2018, and expiring on August 31, 2025. In June 2019, the lease was amended to extend the expiration date to October 31, 2027. Upon the execution of the amendment, which was deemed to be a lease modification, the Company reassessed the lease liability using the discount rate at the modification date and recorded ROU assets for the same amount. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term. The Company has a renewal option to extend the term of the lease for a period of five years beyond the initial term. Under the terms of the lease, the base rent payable with respect to each renewal term will be equal to the prevailing market rental rent as of the commencement of the applicable renewal term. In the event of a default of certain of the Company's obligations under the lease, the Company's landlord would have the right to terminate the lease.

In June 2019, the Company entered into an eight-year operating lease for approximately 32,621 square feet of office space beginning on January 15, 2020 and expiring on January 31, 2028. The Company uses these premises as its new principal executive offices and for general office space. The Company intends to utilize its other currently-leased spaces through the lease expiration dates to conduct the training of its sales team and for manufacturing purposes. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term. The Company has a renewal option to extend the term of the lease for a period of five years beyond the initial term. Under the terms of the lease, the base rent payable with respect to each renewal term will be equal to the prevailing market rental rent as of the commencement of the applicable renewal term. In the event of a default of certain of the Company's obligations under the lease, the Company's landlord would have the right to terminate the lease.

In August 2020, the Company entered into a 38-month operating lease (the New Lease) for approximately 5,693 square feet of warehouse space beginning on October 15, 2020 and expiring on December 31, 2023 (the Initial Term). The Company uses these premises for general warehouse space.

During the years ended December 31, 2020, 2019, and 2018, ROU assets obtained in exchange for new operating lease liabilities were $3.8 million, $1.5 million, and $3.3 million, respectively. As of December 31, 2020 and 2019, the ROU asset has a balance of $7.1 million and $4.2 million, respectively. The operating lease ROU asset is included within the Company's other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company's consolidated balance sheets. During the years ended December 31, 2020, 2019, and 2018, cash paid for amounts included in operating lease liabilities were $1.5 million, $0.9 million, and $0.5 million, respectively. Amortization of the ROU asset was $0.9 million, $0.4 million, and $0.2 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020 and 2019, the weighted-average remaining lease term for the Company's operating leases were 6.6 years and 7.8 years, respectively. The weighted-average discount rate used to determine the present value of the Company's operating leases' future payments was 6.7% and 7.25%, respectively.

Total lease cost for the years ended December 31, 2020, 2019, and 2018 are as follows (in thousands):

	December 31,		
	2020	2019	2018
Lease cost			
Operating lease cost	$ 1,991	$ 1,031	$ 518
Short-term lease cost	95	177	154
Variable lease cost	179	138	6
Total lease cost	$ 2,265	$ 1,346	$ 678

Maturities of operating lease liabilities as of December 31, 2020, are as follows (in thousands):

2021	$ 1,945
2022	1,905
2023	1,803
2024	1,776
2025	1,850
Thereafter	3,862
	13,141
Less: imputed interest	(2,707)
	10,434
Less: operating lease liability, current portion	(1,280)
Operating lease liability, net of current portion	$ 9,154

License Agreement

In October 2013, the Company entered into the License Agreement, pursuant to which AMF licensed the Company certain patents and know-how (collectively, the AMF IP) relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (collectively, the AMF Licensed Products). Under the License Agreement, for each calendar year beginning in 2018, the Company is obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to the Company by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) the Minimum Royalty, payable quarterly. The Minimum Royalty will automatically increase each year after 2018, subject to a maximum amount of $200,000 per year. The Company generated net revenue of $111.5 million, $13.8 million, and $0.7 million during the years ended December 31, 2020, 2019, and 2018, respectively, and recorded related royalties of $4.4 million, $0.6 million, and $0.1 million during the years ended December 31, 2020, 2019, and 2018, respectively. Royalty expense is included in operating expenses in the consolidated statements of comprehensive loss. Accrued royalty of $1.4 million and $0.4 million as of December 31, 2020 and 2019, respectively, is included within accrued liabilities on the Company's consolidated balance sheets.

Legal Matters

On November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (collectively, the Medtronic Affiliates) filed an initial complaint against the Company in the United States District Court for the Central District of California, Case No. 8:19-cv-2115, and amended the complaint on November 26, 2019. The Company refers to this matter as the Medtronic Litigation. The complaint

asserts that the Company's r-SNM System infringes U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324 and 9,821,112 held by the Medtronic Affiliates, and the amended complaint further includes the additional patents 8,738,148; 8,457,758; and 7,774,069 (collectively, the Medtronic Patents). The Medtronic Litigation requests customary remedies for patent infringement, including (i) a judgment that the Company has infringed and is infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) a permanent injunction preventing the Company from infringing the Medtronic Patents, (iv) attorneys' fees, and (v) costs and expenses. The Company believes the allegations are without merit and is vigorously defending itself against them. Given the early stage of the Medtronic Litigation, the Company is unable to predict the likelihood of success of the claims of the Medtronic Affiliates against the Company or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and require the Company to dedicate significant financial resources and management resources to its defense. An adverse ruling against the Company could materially and adversely affect its business, financial position, results of operations or cash flows and could also result in reputational harm. Even if the Company is successful in defending against these claims, the Medtronic Litigation could result in significant costs, delays in future product developments, reputational harm or other collateral consequences.

On March 16, 2020, the Company filed seven petitions before the United States Patent and Trademark Office (USPTO) requesting inter partes review (IPR) to contest the validity of each of the Medtronic patents that Medtronic has alleged are being infringed by the Company. In September 2020, the USPTO decided that it will accept or "institute" the IPR process for six of the seven patents, finding that the Company had demonstrated a reasonable likelihood that at least one, if not all, of the claims of these six patents are invalid. The Company is currently in the IPR discovery process. The USPTO will usually render a decision on the validity of contested patents within twelve months of instituting the review. The Company filed a motion to stay the proceedings before the United States District Court for the Central District of California pending resolution of the IPR process. The Company's motion was granted by the court on May 8, 2020.

In addition to the Medtronic Litigation, the Company is and may continue to be involved in claims, legal proceedings, and investigations arising out of its operations in the normal course of business.

Note 5. Long-Term Debt

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

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

In October 2018, the Company and Silicon Valley Bank entered into an amendment to the Loan Agreement (the Loan Amendment) in connection with which the Company requested the full $5.0 million from Tranche B and the full $5.0 million from Tranche C. The Company received the $10.0 million from both tranches in October 2018. Pursuant to the Loan Amendment, Silicon Valley Bank agreed to (i) extend the interest only period from June 30, 2019 to December 31, 2019, without requiring the receipt of the Company's PMA in the United States for the r-SNM System, and (ii) make Tranche C available immediately instead of January 1, 2019. In addition, as a result of the Company's request of the full $5.0 million from Tranche B and the full $5.0 million from Tranche C, the maturity of the Term Loan has been automatically extended to December 1, 2021. The transaction was accounted for as a debt modification. See Note 6 for discussion regarding stock warrants granted in connection with the Term Loan.

In December 2019, the Company and Silicon Valley Bank entered into a second amendment to the Loan Agreement (the Second Amendment). Pursuant to the Second Amendment, Silicon Valley Bank agreed to extend the interest only period from December 31, 2019 to December 31, 2020. In connection with the Second Amendment, the Company paid Silicon Valley Bank a non-refundable fee of $0.2 million. The transaction was accounted for as a debt modification.

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

All obligations under the Term Loan are secured by a first priority lien on substantially all of the Company's assets, excluding intellectual property assets and more than 65% of the shares of voting capital stock of any of its foreign subsidiaries. The Company has agreed with Silicon Valley Bank not to encumber its intellectual property assets without Silicon Valley Bank's prior written consent unless a security interest in the underlying intellectual property is necessary to have a security interest in the accounts and proceeds that are part of the assets securing the Term Loan, in which case the Company's intellectual property shall automatically be included within the assets securing the Term Loan. As of December 31, 2020, the Company was in compliance with all debt covenant requirements under the Term Loan.

Debt, net of unamortized debt issuance costs, consists of the following (in thousands) at:

	December 31,	
	2020	2019
Debt, principal	$ 20,000	$ 20,000
Accrued loan fees	1,500	1,500
Debt, total	21,500	21,500
Less: unamortized debt issuance costs	(390)	(1,164)
Debt, net of unamortized debt issuance costs	$ 21,110	$ 20,336

Expected future principal payments for the term loan as of December 31, 2020, are as follows (in thousands):

2021	$	21,500
	$	21,500

All obligations under the Term Loan, including accrued interest, prepayment fees, and the minimum final payment, consisting of a 7.5% premium principal amount, were repaid in full in January 2021 (see Note 11).

Note 6. Stockholders' Equity

Preferred Stock

Prior to the IPO, the Company had outstanding 12,219,315 shares of convertible preferred stock. Upon closing of the Company's IPO on October 31, 2018, all shares of outstanding convertible preferred stock were automatically converted to 15,813,297 shares of the Company's common stock. As of December 31, 2020, the Company is authorized to issue 10,000,000 shares of preferred stock with a par value of $0.0001 per share.

Common Stock

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

Voting

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

Dividends

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

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

Liquidation Rights

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

Redemption Rights

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

Preemptive Rights and Conversion Rights

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

Stock-Based Compensation Expense

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

	Years Ended December 31,		
	2020	2019	2018
Research and development	$ 3,457	$ 1,725	$ 197
General and administrative	5,852	3,950	361
Sales and marketing	5,786	3,045	48
	$ 15,095	$ 8,720	$ 606

Stock Option Activity

2014 Stock Option Plan

In 2014, the Company established its 2014 Stock Option Plan (the 2014 Plan), which provides for the granting of stock options to employees, directors, and consultants of the Company. As of December 31, 2020 and 2019, a total of 3,131,624 and 3,156,295 shares have been reserved for issuance under the 2014 Plan, respectively. As of December 31, 2020 and 2019, there were no shares available for grant under the 2014 Plan. The 2018 Omnibus Incentive Plan was adopted upon our IPO and replaced the 2014 Stock Option Plan for future grants.

2018 Omnibus Incentive Plan

On October 18, 2018, the Company adopted the 2018 Omnibus Incentive Plan (the 2018 Plan), under which the Company may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which it competes. The 2018 Plan provides for awards based on shares of the Company's common stock. Subject to adjustment by the Company's board of directors, the total number of shares authorized to be awarded under the 2018 Plan may not exceed 4,562,317. As of December 31, 2020 and 2019, there were 1,678,326 and 1,965,500 shares available for grant under the 2018 Plan, respectively.

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

	December 31,	
	2020	2019
Options outstanding under the 2014 Plan	501,598	1,126,140
Options and restricted stock-based awards outstanding under the 2018 Plan	2,477,929	2,560,232
Options and restricted stock-based awards remaining under the 2018 Plan for future issuance	1,678,326	1,965,500
	4,657,853	5,651,872

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

	Years Ended December 31,		
	2020	**2019**	**2018**
Expected term (in years)	6.05	5.07 - 6.16	5.00 - 6.96
Stock volatility	72.01%	70.02% - 77.52%	68.04% - 77.03%
Risk-free interest rate	1.37%	1.42% - 2.56%	2.26% - 3.07%
Dividend rate	—	—	—

The Company used the simplified method of determining the expected term of stock options as the Company believes this represents the best estimate of the expected term of a new option. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have sufficient trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments, whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The assumptions regarding the expected term of the options and the expected volatility of the stock price are subjective, and these assumptions have a significant effect on the estimated fair value amounts. The weighted-average grant date fair value of options granted was $18.56, $13.79, and $3.62 for the years ended December 31, 2020, 2019, and 2018 respectively.

As of December 31, 2020 and 2019, there was $11.6 million and $19.5 million, respectively, of total unrecognized compensation cost related to unvested stock options that is expected to be recognized over a weighted-average period of approximately 2.4 years and 3.2 years, respectively.

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

	Number of Options	Weighted-Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at December 31, 2017	903,857	$ 1.18	
Options granted	668,380	3.55	
Options exercised	(55,840)	1.47	$ 23 (1)
Options forfeited	(2,050)	1.23	
Outstanding at December 31, 2018	1,514,347	2.22	
Options granted	1,671,044	21.28	
Options exercised	(281,744)	1.79	$ 7,386 (1)
Options forfeited	(56,546)	13.43	
Outstanding at December 31, 2019	2,847,101	13.22	
Options granted	5,000	29.03	
Options exercised	(767,792)	5.05	$ 25,066 (1)
Options forfeited	(129,066)	20.20	
Outstanding at December 31, 2020	1,955,243	$ 16.01	$ 66,302 (2)
Options exercisable at December 31, 2020	906,457	$ 14.30	$ 32,287 (2)

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

(2) Represents the total difference between the Company's closing stock price on the last trading day of 2020 and the stock option exercise price, multiplied by the number of in-the-money options as of December 31, 2020. The amount of intrinsic value will change based on the fair market value of the Company's stock.

The weighted-average remaining contractual term of options outstanding and exercisable is 7.7 years and 7.6 years at December 31, 2020 and 2019, respectively.

Restricted Shares Awards Activity

As of December 31, 2020 and 2019, there was $22.6 million and $11.8 million, respectively, of total unrecognized compensation cost related to unvested restricted shares awards that is expected to be recognized over a weighted-average period of approximately 3.3 years and 3.3 years, respectively.

The following table summarizes restricted shares awards activity:

	Number of Restricted Shares Awards	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2017	—	$ —
Restricted shares awards granted	50,000	14.48
Outstanding at December 31, 2018	50,000	14.48
Restricted shares awards granted	580,667	24.08
Restricted shares awards vested	(27,551)	18.80
Restricted shares awards forfeited	(16,950)	21.09
Outstanding at December 31, 2019	586,166	23.59
Restricted shares awards granted	502,500	37.68
Restricted shares awards vested	(174,890)	23.29
Restricted shares awards forfeited	(96,593)	28.83
Outstanding at December 31, 2020	817,183	$ 31.70

Restricted Stock Units Activity

As of December 31, 2020 and 2019, there was $1.2 million and $4.3 million, respectively, of total unrecognized compensation cost related to unvested restricted stock units that is expected to be recognized over a weighted-average period of approximately 0.9 years and 1.5 years, respectively.

The following table summarizes restricted stock units activity:

	Number of Restricted Stock Units	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2018	—	$ —
Restricted stock units granted	248,104	21.48
Outstanding at December 31, 2019	248,104	21.48
Restricted stock units granted	8,000	29.03
Restricted stock units vested	(46,336)	14.19
Restricted stock units forfeited	(2,667)	14.19
Outstanding at December 31, 2020	207,101	$ 23.49

Stock Subscriptions Receivable

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

Stock Warrants

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

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

On July 16, 2019, the Company issued and sold 32,529 shares of its common stock to SVB Financial Group (SVB) in connection with the exercise by SVB of its right to purchase 40,000 shares of its common stock under that certain warrant, dated as of February 6, 2018. The exercise price per share was $7.50, and was paid by SVB via forfeiture of shares pursuant to a cashless exercise provision in the warrant.

On May 29, 2019, the Company issued and sold 31,071 shares of its common stock to Life Science Loans II, LLC (Life Science Loans) in connection with the exercise by Life Science Loans of its right to purchase 40,000 shares of its common stock under that certain warrant, dated as of February 6, 2018. The exercise price per share was $7.50, and was paid by Life Science Loans via forfeiture of shares pursuant to a cashless exercise provision in the warrant.

No warrants were outstanding at December 31, 2020.

Note 7. Noncontrolling Interest

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

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

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

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

Note 8. Income Taxes

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

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

	December 31,	
	2020	2019
Compensation accruals	$ 592	$ 404
Depreciation and amortization	145	48
Lease liability	901	252
Net operating loss carryforwards	59,176	41,564
Other	4,438	3,752
Total deferred tax assets	65,252	46,020
Less: valuation allowance	(65,252)	(46,020)
Total net deferred tax assets	$ —	$ —

At December 31, 2020, the Company had federal and California net operating loss (NOL) carryforwards of approximately $213.5 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 performed an analysis of changes in ownership for purposes of these Internal Revenue Code sections. Based on the study performed in 2020, the Company determined that an ownership change occurred in 2014, 2018 and 2019. The total reduction to the net operating loss carryforwards and R&D credit was $12.2 million and $1.5 million, respectively. The total reduction of the net operating loss carryforwards was offset by valuation allowance, and there was no impact to tax expense related to the limitation. Future ownership changes could impact the Company's ability to utilize NOL carryforwards. The Company has recorded a full valuation allowance against its otherwise recognizable deferred income tax assets as of December 31, 2020 and 2019. The Company has determined, after evaluating all positive and negative historical and prospective evidence, that it is more likely than not that the deferred income tax assets will not be realized. The valuation allowance increased by $19.2 million for the year ended December 31, 2020, from $46.0 million to $65.3 million. During fiscal year 2020, we corrected the prior year balance of deferred tax assets relating to tax loss carryforwards as well as the valuation allowance related to those assets by an equal and offsetting amount. As a result, the tax loss carryforwards and valuation allowance previously reported as of December 31, 2019 have both been decreased in the table above by $3.9 million and corresponding revisions have been made to the prior year tax benefit reconciliation. These immaterial adjustments to the disclosures had no effect on the consolidated balance sheets, statements of operations and cash flows for any periods presented. The Company's NOL carryforwards were generated from domestic operations. The federal NOLs from the 2013-2017 tax years will expire between 2033 and 2037 and NOLs from 2018-2020 will carryover indefinitely. The state NOLs will expire between 2033 and 2039. Under California Assembly Bill 85, effective June 29, 2020, net operating loss deductions were suspended for tax years beginning in 2020, 2021, and 2022 and the carry forward periods of any net operating losses not utilized due to such suspension were extended. The Company applies the provisions of FASB Accounting Standards Codification (ASC 740-10), "Accounting for Uncertainty in Income Taxes." ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on a tax return. The Company had unrecognized tax benefits of $2.5 million and none as of December 31, 2020 and 2019, respectively, of which $2.5 million and none, respectively, if recognized would not affect the annual effective tax rate as these unrecognized tax benefits would increase deferred tax assets which would be subject to a full valuation allowance. The Company does not believe that the amount of unrecognized tax benefits will change significantly in the next 12 months. There were no interest or penalties to be recognized for the tax years ended December 31, 2020, 2019, and 2018.

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

Balance at December 31, 2019 and 2018	$ —
Deductions based on tax positions related to prior years	—
Additions based on tax positions related to the current year	2,491
Balance at December 31, 2020	$ 2,491

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

	Years Ended December 31,		
	2020	2019	2018
Tax at statutory federal rate	21.0 %	21.0 %	21.0 %
State tax, net of federal benefit	7.0 %	7.0 %	7.0 %
Excess tax benefits related to stock-based compensation	10.3 %	(1.0)%	(0.4)%
Section 382 Limitation	— %	(5.0)%	— %
R&D tax credit 100% reserve	(4.5)%	— %	— %
Change in valuation allowance	(36.8)%	(21.5)%	(27.4)%
Other	3.0 %	(0.5)%	(0.2)%
Effective tax rate	— %	— %	— %

CARES Act

The CARES Act includes provisions to support businesses in the form of loans, grants, and tax changes, among other types of relief. The Company has reviewed the income tax changes included in the CARES Act, which primarily includes the expansion of the carryback period for NOLs, changes to the deduction and limitation on interest, and acceleration of depreciation for Qualified Improvement Property. The Company has analyzed these changes and does not believe there will be a material effect on the Company's income tax provision.

Note 9. Employee Benefit Plan

The Company sponsors a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pre- or post-tax basis. Contributions to the plan by the Company may be made at the discretion of the board of directors. During the years ended December 31, 2020, 2019, and 2018, the Company contributions to the plan amounted to $1.6 million, $1.1 million, and $0.3 million, respectively.

Note 10. Related Party Transactions

The Company has a License Agreement and corresponding royalties incurred with AMF, which is also a stockholder of the Company. For additional information, see Note 4.

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

Note 11. Subsequent Events

Pay-off of Loan Agreement Maturing December 2021

In January 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to the Term Loan were paid in full. The unamortized debt issuance costs of $0.4 million as of December 31, 2020 will be expensed and recognized as interest expense during the three months ending March 31, 2021.

Acquisition of Contura Limited

In February 2021, the Company acquired London-based Contura Limited (Contura) and its flagship product, Bulkamid, for total consideration of $200 million in cash and stock, and a potential future milestone payment of $35 million. Total upfront consideration is comprised of approximately $141.3 million paid in cash and the issuance of 1,096,583 shares of stock. The Company also entered into a manufacturing agreement for the supply of the Bulkamid hydrogel. The Company has rights to a technology transfer after June 30, 2022 that would enable the Company to insource the manufacturing of Bulkamid. The initial accounting for the business combination, including the estimated fair value of assets and liabilities acquired, is incomplete as a result of the timing of the acquisition.

Loan and Security Agreement with Silicon Valley Bank

In February 2021, the Company entered into a $75 million term loan with Silicon Valley Bank (the Loan) maturing February 2024. The Loan provides for monthly interest payments through August 2022, and monthly principal and interest payments from September 2022 through maturity. Outstanding principal balances under the Loan bear interest at the greater of (i) prime rate plus 5.75% or (ii) 9.00%. The Company will be required to make a final payment equal to the original principal amount multiplied by 6.00%.

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

None.

Item 9A. Controls and Procedures.

Limitations on effectiveness of controls and procedures

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

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of December 31, 2020, the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Management's Annual Report on Internal Control Over Financial Reporting

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

Management has conducted, with the participation of our Principal Executive Officer and our Principal Accounting Officer, an assessment, including testing of the effectiveness, of our internal control over financial reporting as of December 31, 2020. Management's assessment of internal control over financial reporting was conducted using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework (2013 Framework). Based on its assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2020. The effectiveness of the Company's internal control over financial reporting as of December 31, 2020 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in its report which is included in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the most recent fiscal quarter covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Axonics Modulation Technologies, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2020, the consolidated statement of mezzanine equity for the year ended December 31, 2018, and the related notes and our report dated March 1, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ BDO USA, LLP
Costa Mesa, California
March 1, 2021

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2020 and delivered to stockholders in connection with our 2021 annual meeting of stockholders.

Item 11. Executive Compensation.

The information required by this Item 11 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2020 and delivered to stockholders in connection with our 2021 annual meeting of stockholders.

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

The information required by this Item 12 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2020 and delivered to stockholders in connection with our 2021 annual meeting of stockholders.

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

The information required by this Item 13 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2020 and delivered to stockholders in connection with our 2021 annual meeting of stockholders.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2020 and delivered to stockholders in connection with our 2021 annual meeting of stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

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

1. Consolidated Financial Statements:

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

2. Financial Statement Schedule:

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

3. Exhibits:

EXHIBIT INDEX

		Incorporated by Reference				
Exhibit Number	**Exhibit Title**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith (X)**
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-38721	3.1	11/05/2018	
3.2	Amended and Restated Bylaws.	8-K	001-38721	3.2	11/05/2018	
4.1	Specimen certificate evidencing shares of common stock of the Registrant.	S-1	333-227732	4.1	10/5/2018	

4.2	Fourth Amended and Restated Investors' Rights Agreement, dated March 29, 2018, by and among the Registrant and the Investors party thereto.	S-1	333-227732	4.2	10/5/2018	
4.3	Amendment to Fourth Amended and Restated Investors' Rights Agreement, dated October 17, 2018, by and among the Registrant and the Investors party thereto.	S-1/A	333-227732	4.3	10/22/2018	
4.4	Description of Securities.					X
10.1+	2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.8	10/22/2018	
10.2+	Form of Option Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.9	10/22/2018	
10.3+	Form of Restricted Shares Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.10	10/22/2018	
10.4+	Form of RSU Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.11	10/22/2018	
10.5+#	Form of Debt Forgiveness Agreement and Cancellation of Note (Tax Withholding-Shares).	S-1	333-227732	10.28	10/5/2018	
10.6+#	Form of Debt Forgiveness Agreement and Cancellation of Note (Tax Withholding-Cash).	S-1	333-227732	10.29	10/5/2018	
10.7	Loan and Security Agreement, dated February 6, 2018, by and between Silicon Valley Bank.	S-1	333-227732	10.16	10/5/2018	
10.8	Amendment to Loan and Security Agreement, dated October 22, 2018, by and between Silicon Valley Bank and the Registrant.	S-1/A	333-227732	10.31	10/22/2018	
10.9	Second Amendment to Loan and Security Agreement, dated as of December 30, 2019, by and between Axonics Modulation Technologies, Inc. and Silicon Valley Bank.	8-K	001-38721	1.1	1/2/2020	
10.10	Lease, dated November 30, 2017, by and between The Irvine Company LLC and the Registrant.	S-1	333-227732	10.13	10/5/2018	
10.11	First Amendment to Lease, dated April 12, 2018, by and between The Irvine Company LLC and the Registrant.	S-1	333-227732	10.14	10/5/2018	
10.12	Second Amendment to Lease, dated July 11, 2018, by and between The Irvine Company LLC and the Registrant.	S-1	333-227732	10.15	10/5/2018	

10.13	Third Amendment to Lease, dated June 28, 2019, by and between The Irvine Company LLC and Axonics Modulation Technologies, Inc.	8-K	001-38721	10.1	7/12/2019	
10.14+	Executive Employment Agreement, dated June 5, 2019, by and between Raymond W. Cohen and the Registrant.	10-Q	001-38721	10.2	8/5/2019	
10.15+	Executive Employment Agreement, dated June 5, 2019, by and between Dan L. Dearen and the Registrant.	10-Q	001-38721	10.3	8/5/2019	
10.16+	Executive Employment Agreement, dated June 5, 2019, by and between Rinda Sama and the Registrant.	10-Q	001-38721	10.4	8/5/2019	
10.17	License Agreement, dated October 1, 2013, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.	S-1	333-227732	10.1	10/5/2018	
10.18	First Amendment to License Agreement, dated February 19, 2014, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.	S-1	333-227732	10.2	10/5/2018	
10.19	Second Amendment to License Agreement, dated February 25, 2014, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.	S-1	333-227732	10.3	10/5/2018	
10.20	Side Letter, dated October 1, 2013, by and between the Alfred E. Mann Foundation for Scientific Research and the Registrant.	S-1	333-227732	10.4	10/5/2018	
10.21	Form of Indemnification Agreement by and between the Registrant and its directors and officers.	S-1/A	333-227732	10.12	10/22/2018	
21.1	List of Subsidiaries.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X

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

\+ Indicates management contract or compensatory plan.

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

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

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

AXONICS MODULATION TECHNOLOGIES, INC.

Date: March 1, 2021

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

POWER OF ATTORNEY

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

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

Date: March 1, 2021	By:	/s/ Raymond W. Cohen Raymond W. Cohen Chief Executive Officer and Director (Principal Executive Officer)
Date: March 1, 2021	By:	/s/ Dan L. Dearen Dan L. Dearen President and Chief Financial Officer (Principal Financial and Accounting Officer)
Date: March 1, 2021	By:	/s/ Michael H. Carrel Michael H. Carrel Chairman of the Board and Director
Date: March 1, 2021	By:	/s/ Jane E. Kiernan Jane E. Kiernan Director
Date: March 1, 2021	By:	/s/ Robert E. McNamara Robert E. McNamara Director
Date: March 1, 2021	By:	/s/ Nancy Snyderman, M.D., FACS Nancy Snyderman, M.D., FACS Director
Date: March 1, 2021	By:	/s/ David M. Demski David M. Demski Director

Exhibit 4.4

Description of the Registrant's Securities Registered Under Section 12 of the Securities Exchange Act of 1934

The following is a description of the capital stock of Axonics Modulation Technologies, Inc. Our common stock, par value $0.0001 per share, is registered under Section 12 of the Securities Exchange Act of 1934, as amended, while our preferred stock, par value $0.0001 per share, is not so registered. This description does not describe every aspect of our capital stock and is subject to, and qualified in its entirety by reference to, the provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, each as currently in effect, each of which is incorporated by reference as an exhibit to our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, to which this Description of Capital Stock is filed as an exhibit. References to "we," "our," and "us" refer to Axonics Modulation Technologies, Inc. and its consolidated subsidiaries.

Authorized Capital Stock

Our authorized capital stock consists of 50,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the trading symbol "AXNX." The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

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

Voting

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

Dividends

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

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

Liquidation Rights

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

Redemption Rights

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

Preemptive Rights and Conversion Rights

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

Registration Rights

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

The Rights Agreement grants the parties thereto certain registration rights in respect of "registrable securities" held by them, which securities include (i) shares of our common stock issued or issuable upon conversion of shares of our preferred stock, (ii) shares of our common stock issued as a dividend or other distribution with respect to the shares in the foregoing clause (i), and (iii) shares of our common stock held by Alfred E. Mann Foundation for Scientific Research 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 of 1933, as amended, or the Securities Act, when the applicable registration statement is declared effective. Under the Rights Agreement, we generally are required to pay all registration expenses, other than underwriting discounts and commissions, relating to any demand, Form S-3 or piggyback registration by the holders of registrable securities, subject to certain limitations. The Rights Agreement also includes customary indemnification and procedural terms.

Demand Registration Rights

The holders of more than 30% of the registrable securities then outstanding may request that we file a registration statement on Form S-1 registering all or a portion of their registrable securities. Under specified circumstances, we have the right to defer filing of a requested registration statement for a period of not more than 90 days, which right may not be exercised more than once during any twelve-month period. These registration rights are subject to additional conditions and limitations, including the right of the underwriters of any underwritten offering to limit the number of shares included in any such registration under certain circumstances, and our right to decline to effect such registration if the holders requesting holders propose to sell registrable securities at an aggregate price to the public of less than $10.0 million.

Form S-3 Registration Rights

If we are eligible to file a registration statement on Form S-3, the holders of the registrable securities then outstanding have the right to request that we file additional unlimited registration statements for such holders on Form S-3. Under specified circumstances, we have the right to defer filing of a requested registration statement for a period of not more than 90 days, which right may not be exercised more than once during any twelve-month period. These registration rights are subject to additional conditions and limitations, including the right of the underwriters of any underwritten offering 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 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 of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement.

Expiration of Registration Rights

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

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

Delaware Anti-Takeover Law

We are subject to Section 203 of the DGCL ("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 Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws may make a change in control of our company more difficult and could delay, defer or prevent a tender offer or other takeover attempt that a stockholder might consider to be in its best interest, including takeover attempts that might result in the payment of a premium to stockholders over the market price for their shares. These provisions also may promote the continuity of our management by making it more difficult for a person to remove or change the incumbent members of our board of directors.

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

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

Director Vacancies. Our Amended and Restated Certificate of Incorporation authorizes only our board of directors to fill vacant directorships.

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

Special Meetings of Stockholders. Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that special meetings of our stockholders may only be called by the Chair of the board, our Chief Executive Officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, whether or not there exist any vacancies in previously authorized directorships.

Advance Notice Procedures for Director Nominations. Our Amended and Restated Bylaws establish advance notice procedures for stockholders seeking to nominate candidates for election as directors at an annual or special meeting of stockholders. Although our Amended and Restated Bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates to be elected at an annual meeting, our Amended and Restated 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 Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that any action required or permitted to be taken by the stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by any consent in writing in lieu of a meeting of such stockholders, subject to the rights of the holders of any series of preferred stock.

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

Conflicts of Interest

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

Limitations on Liability and Indemnification Matters

Our Amended and Restated Certificate of Incorporation contains 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 Amended and Restated Bylaws 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 provided for in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws. 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 Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions set forth in our Amended and Restated Certificate of Incorporation and Amended and Restated 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.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"), may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, we have 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.

Exhibit 21.1

List of Subsidiaries of
Axonics Modulation Technologies, Inc.

Name of Subsidiary	Jurisdiction of Incorporation or Organization
Axonics Europe, S.A.S.	France
Axonics Modulation Technologies, U.K. Limited	England and Wales
Axonics Modulation Technologies Australia Pty Ltd	Australia

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Axonics Modulation Technologies, Inc.
Irvine, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-234546) and Form S-8 (No.333-228170) of Axonics Modulation Technologies, Inc. of our reports dated March 1, 2021, relating to the consolidated financial statements and the effectiveness of Axonics Modulation Technologies, Inc.'s internal control over financial reporting, which appears in this Form 10-K.

/s/ BDO USA, LLP
Costa Mesa, California

March 1, 2021

Exhibit 31.1

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

I, Raymond W. Cohen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 1, 2021

By: /s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer and Director

(Principal Executive Officer)

Exhibit 31.2

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

I, Dan L. Dearen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 1, 2021

By: /s/ Dan L. Dearen

Dan L. Dearen

President and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of Axonics Modulation Technologies, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 1, 2021

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

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

Exhibit 32.2

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

In connection with the Annual Report of Axonics Modulation Technologies, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 1, 2021

By: /s/ Dan L. Dearen
Dan L. Dearen
President and Chief Financial Officer
(Principal Financial Officer)

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