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, 2021
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____
Commission File Number: 001-38721

Axonics, Inc.
(Exact name of registrant as specified in its charter)

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

(949) 396-6322
(Registrant's telephone number, including area code)

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒
The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $2,893.0 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $63.41 per share for such date.
As of February 25, 2022, 46,956,973 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, 2021. Only those portions of any such definitive proxy statement that are specifically incorporated by reference herein shall constitute a part of this Annual Report on Form 10-K.

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Special Note Regarding Forward-Looking Statements

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

- 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;
- 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; and
- reduction or interruption in our supply chain.

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, 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 our r-SNM System will generate the 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 actual or alleged failure to comply with applicable requirements could harm our business.
- We may not receive the necessary clearances or approvals for modifications to our products, and failure to do so would adversely affect our ability to grow our business.
- The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies.
- Failure to comply with post market regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw our products from the market.

- We or any of our suppliers or 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.
- Litigation or third-party claims of various types could be asserted against us, which could require us to spend significant time and money and could affect our business operations and/or stock price.
- 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.
- 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 is developing and commercializing novel products for adults with bladder and bowel dysfunction, including: (i) implantable sacral neuromodulation (SNM) systems to treat urinary urge incontinence (UUI) and urinary urgency frequency (UUF), together referred to as overactive bladder (OAB), as well as fecal incontinence (FI), and non-obstructive urinary retention (UR); and (ii) a urethral bulking agent to treat female stress urinary incontinence (SUI).

SNM System

We believe our proprietary rechargeable SNM system (r-SNM System), the first to be marketed worldwide, offers significant advantages, and is well positioned to capture market share and grow the market for SNM therapy.

Our r-SNM System is designed to last 15 or more years in the human body, is only 5cc in volume, offers broad MRI access, ease of use, intuitive programmers, and the longest interval between recharging 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 premarket approval (PMA) by the FDA. We also have marketing approvals for the r-SNM System in Europe, Canada, and Australia for all relevant clinical indications.

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 symptom relief. We believe that our r-SNM System offers therapeutic benefits and competitive advantages compared to the only other currently available SNM technologies, InterStim II and InterStim Micro, both offered by Medtronic. As a result of the longevity of our 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 the non-rechargeable InterStim II, potentially reducing the risks of surgery and associated infections.

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 implantable neurostimulator (INS) enclosure of our r-SNM System. This method enables us to incorporate a small battery and recharging coil into our INS. The ceramic portion of the implantable device allows for short range wireless communication to the patient remote control. Our INS is half the weight of InterStim II and offers twice the recharging interval (one month vs. two weeks) of InterStim Micro, Medtronic's rechargeable INS. 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 wireless patient remote control that does not require recharging or replacement batteries. We also designed and custom built a clinician programmer that guides the implanting physician through lead placement and stimulation programming.

We intend to continue to invest in research and development activities to expand our suite of products for SNM therapy. To that end, in late June 2021, we filed a PMA supplement with the FDA for a long-lived non-rechargeable SNM device that, among other things, utilizes a primary cell battery.

We focus most 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.

Urethral Bulking Agent

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

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

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. Many patients present with both SUI and UUI, referred to as mixed incontinence.

While bulking products have been on the market for over a decade, the bulking effect of the legacy bulking products has limitations, primarily due to difficulty in administration and the variability in the volume of bulking material injected, resulting in relatively short-lived durability and relief for patients. Legacy bulking agents contain microparticles, which according to clinical literature 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 legacy particulate-based bulking agents. It is a unique and patented non-particulate hydrogel that is injected into the urethral wall to

restore the natural closing pressure of the urethra. It is a simple, quick, and easy-to-learn and perform procedure that can be performed in either a physician's office or an outpatient facility.

Bulkamid is biocompatible, consisting of 97.5% water, and does not induce a chronic inflammatory response. Bulkamid's bulking effect is aided by the volume of each injection being predictable, controllable, and precise. Bulkamid retains its bulking characteristics for a number of years, thereby maintaining efficacy and providing women with long lasting relief of their SUI symptoms. Bulkamid is supported by extensive clinical validation, with over 90,000 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 treating SUI and take share from invasive surgical sling procedures. Our new product further increases our value to physicians as we can now offer customers best-in-class solutions for patients with all types of urinary and fecal incontinence.

Bulkamid is currently sold through a direct salesforce in the United States, Germany, United Kingdom, and the Nordic countries and through distributors in certain international markets around the world.

Our Success Factors

We believe that our continued growth 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 was introduced in 1997, we estimate hundreds of thousands of patients have been implanted with legacy competitive SNM devices. In 2021, we believe that approximately 48,000 patients were implanted with either an Axonics r-SNM or a Medtronic InterStim device, corresponding to an approximately $750 million SNM market in the United States. We believe that the introduction of highly differentiated SNM products 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, 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 at least 15 years. As a result, our r-SNM System offers several benefits not found in the legacy competitive device, the non-rechargeable 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. We believe a long-lived system significantly improves a patient's experience and reduces the risks of replacement surgery and associated infections. In addition, by reducing the number of replacement surgeries, physicians and facilities can utilize their resources more efficiently and potentially reduce overall costs to the healthcare system. Our r-SNM System was also the first SNM system to allow full-body MRI scans under certain conditions.
- ***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 believe clinical data is important and will aid in driving broad-based adoption of SNM therapy.
- ***Substantial field-based sales and clinical teams.*** We hired and trained sales representatives and clinical specialists with strong backgrounds and experience in SNM therapy and other neurostimulation applications, and who have existing relationships with urologists and urogynecologists. We anticipate that this investment in our commercial team will enable us to compete effectively and gain market share, as we expect relationships, expertise and patient outcomes are important factors for widespread adoption of our current and future SNM Systems.

- ***A deep understanding of our target market.*** We formed our company by assembling an experienced team with significant in-depth knowledge in developing and marketing medical devices. From the outset, we spent significant time understanding the unmet needs of patients and physicians through patient interviews and engagement of physicians and key opinion leaders. By utilizing this market knowledge and initially focusing solely on SNM, we have been able to efficiently navigate the product development, clinical and regulatory requirements for our r-SNM System.
- ***Comprehensive and broad intellectual property portfolio.*** Our r-SNM System is supported by a nucleus of issued patents and patent applications that we license from 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, 2021, we own 44 issued U.S. patents and 141 issued foreign patents, and 21 pending U.S. patent applications and 24 pending foreign patent applications. We also license from AMF 25 issued U.S. patents and three pending U.S. patent applications, as well as 50 issued foreign patents and six 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 women of all ages but becomes more prevalent with age and can have a significant impact on daily life, affecting activities, relationships, and emotional well-being. The prevalence of SUI in adult women in the U.S. is 23%, or approximately 29 million women. Most women are unaware of bulking as a treatment option for SUI and based on the efficacy and durability of Bulkamid, we believe the SUI market is poised for significant growth in the years ahead. We believe that legacy bulking agents have not achieved widespread adoption due to limited efficacy. 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.*** Bulkamid procedures are done by the same type of physicians that perform SNM procedures and we expect to leverage our large commercial footprint and existing relationships to drive adoption. We believe Bulkamid 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 strong clinical results. With Bulkamid, we now offer physician customers and their patients best-in-class solutions to treat both OAB and SUI.
- ***Experienced management team.*** Our senior management team has over 150 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 45,000 physicians addressing OAB and FI in the United States, only approximately 2,000 or less than 5% are currently trained to perform, or are actively performing SNM procedures. We intend to help physicians in their direct-to-patient outreach and are pursuing Axonics-sponsored direct-to-consumer marketing initiatives. We believe this will increase the number of patients seeking treatment and ultimately undergoing SNM procedures.
- ***Continue to develop a commercialization infrastructure with a dedicated direct sales team.*** We intend to focus the significant majority of our sales and marketing efforts in the United States since we believe that approximately 90% of the annual global SNM sales are generated in this market. To achieve our commercialization goals, we plan to continue to expand the number of sales representatives and clinical specialists, and to provide them with sufficient resources to achieve success.

- ***Continuously innovate to introduce enhanced SNM product offerings.*** We intend to continue to invest in research and development activities to expand our suite of products for SNM therapy. To that end, in late June 2021, we filed a PMA supplement with the FDA for a long-lived non-rechargeable SNM device that, among other things, utilizes a primary cell battery.
- ***Further penetrate our initial target market by promoting patient and practice awareness.*** Currently, we estimate that less than three percent of patients worldwide that could benefit from SNM therapy have been implanted with an SNM device. We believe that there are several factors that influence this low historical penetration of the potential market. First, even after patients were made aware of SNM therapy by a physician, many patients elected not to undergo the procedure due to the limitations of the legacy product, such as the need for multiple INS replacement surgeries and the large device size. Second, we believe there is a large potential patient population suffering from OAB and/or FI that is unaware of SNM therapy. Third, we believe that more physicians need to offer SNM. We intend to educate physicians that are unfamiliar with the benefits of SNM therapy and the attractiveness to patients of our r-SNM System. We intend to increase physician and patient awareness through engagement, direct patient outreach, presentation of clinical data at medical conferences and publication of clinical data in peer reviewed journals.
- ***Expand our product offerings with complementary products in our market.*** We believe our acquisition of Bulkamid is highly synergistic and positions us to become a global leader in urinary incontinence solutions. We expect to leverage our existing commercial footprint of over 290 sales and clinical specialists in the United States and Europe who call on urogynecologists and urologists for SNM, the same type of physicians who treat SUI. We also believe that extending our urology platform to offer solutions for both OAB and SUI will enhance our value proposition and drive additional SNM sales.

Our Markets

The market for SNM therapy is large and growing. Our SNM target market consists of approximately 18 million adults in the United States and Europe who suffer from symptoms of UUI, UUF, FI, and UR who have progressed through the care pathway that are ready to be treated with SNM therapy.

The market for SUI therapy is highly underpenetrated, with approximately 29 million women suffering from SUI in the United States. We estimate that less than half of women have sought medical treatment, most of whom were offered conservative therapy or opted for no treatment due to a lack of non-invasive treatment options with high efficacy.

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

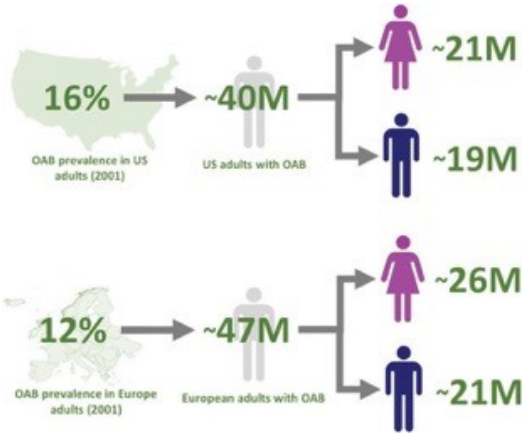
We believe that the U.S. SNM market is now approximately $750 million, representing approximately 48,000 annual patient implants. We believe the SNM market will continue to increase for the foreseeable future driven by increased awareness and education of SNM therapy, greater expectations for quality of life, and improved patient attitudes toward receiving medical attention. In addition, market growth is anticipated to accelerate due to continued innovation and the introduction of new efficacious and long-lived products for SNM therapy. We believe that this represents a compelling opportunity for our r-SNM System to capture market share and grow the market for SNM therapy.

Overview of Overactive Bladder

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

Based on a study published in 2003 by Stewart WF et al., whereby phone-based surveys of 5,204 people were conducted from November 2000 to January 2001, 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.



We believe these surveys are 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.

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

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

If the physician is able to identify an underlying cause of OAB, the physician will then 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 due to the benign enlargement of the prostate accounting for over 60% of the male OAB population. 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. Accordingly, we estimate that a modest percentage of men who suffer from OAB are treatable with SNM therapy.

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

Path to Treatment

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

In the United States, of the approximately 40 million adult patients with symptoms of OAB, we believe that approximately 16 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 19 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, is approximately 35 million.

Of the approximately 16 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 19 million patients who seek medical attention for the treatment of symptoms of OAB, we believe that approximately 8 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 million patients 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 non-implantable Percutaneous Tibial Nerve Stimulation (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 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 $2.8 billion in 2021. Anticholinergics such as Oxybutynin, Vesicare, Detrol, Oxytrol, Enablex, and Sanctura are the most commonly prescribed medications. However, patients often do not fully comply with their drug prescriptions, due to perceived inefficacy and side effects. Mirabegron and Vibegron are the only available beta-3-adrenergic agonists that targets the bladder muscles and reduces bladder contractions to treat OAB. Physicians may also prescribe Tricyclic antidepressants such as Duloxetine and Imipramine, which are not FDA approved to treat the symptoms of OAB, but have been shown to relax the muscles in the bladder and reduce urgency.

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

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

Third-Line Therapies

Sacral Neuromodulation

Historically, SNM therapy has been the most common form of third-line therapy treatment for OAB. Medtronic's InterStim I was approved by the FDA to treat the symptoms of UUI in 1997 and UUF in 1999. InterStim II was approved to treat the symptoms of OAB by the FDA in 2005, and to treat the symptoms of FI in 2011. These systems have been implanted in hundreds of thousands of patients, with a majority of all implants having taken place in the United States.

BOTOX Injections

BOTOX injections into the bladder muscle were approved for treatment of symptoms of OAB by the FDA in 2013. BOTOX is injected through a cystoscopic procedure in a clinician's office or the outpatient surgery setting, and BOTOX treats OAB by blocking the signal from the bladder nerves to the bladder muscle. Key adverse events

include recurrent urinary tract infections and self-catheterization due to inability to void. BOTOX injections are typically required every six to 12 months to maintain reduction of OAB symptoms. We believe the frequent need for injections and the adverse event profile are deterrents to initial and long-term preference for BOTOX injections, as evidenced by an approximately 60% rate of cessation of BOTOX injections at three years, according to a retrospective study by Mohee et al. 2012.

Percutaneous Tibial Nerve Stimulation

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

Overview of Fecal Incontinence

FI is the inability to control bowel function, causing involuntary or accidental leakage from the rectum. Stimulation of the sacral nerves can reduce incontinence episodes, urgency, and frequency in people suffering from FI, and is an approved therapy for the treatment of FI in the United States and Europe. Moreover, a significant population of people suffering from FI also exhibit symptoms of OAB. SNM therapy can alleviate symptoms in patients suffering from either or both OAB and FI. 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, 8.3% of the adult population in the United States exhibited symptoms of FI, or approximately 18 million adults. In this survey, FI prevalence was assessed as the occurrence of at least one incontinence episode during the past month. In addition, according to The National Institute for Health and Care Excellence in the United Kingdom, of the approximately 391 million adult population in Europe in 2007, between 1.0% and 10.0% exhibited symptoms of FI. Based on this data, we have assumed that 5.0% of the adult population in Europe at that time, or approximately 20 million people, exhibited symptoms of FI.

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

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

Path to Treatment

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. 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 3.0 million are SNM addressable and do not suffer from FI as a result of a condition such as neurological disease, inflammatory disease and severe anatomical defects that require a different treatment path.

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.

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 the United States, Europe, Canada, and Australia for all relevant clinical indications.

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

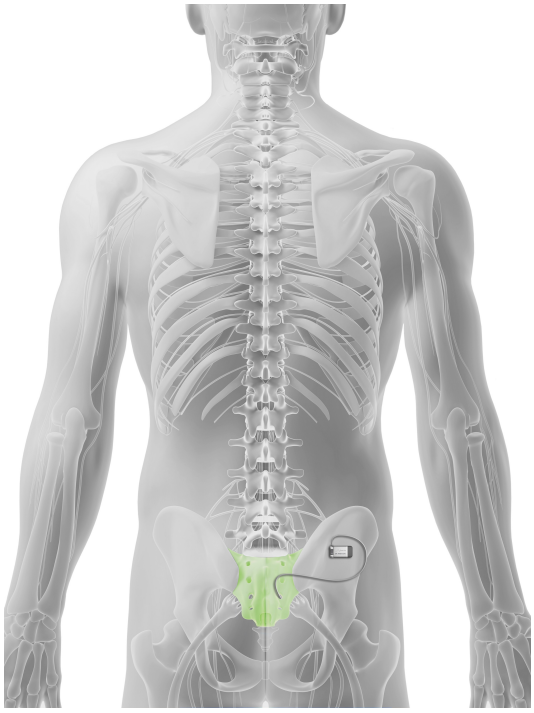
External Components for Patient

- 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 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.
- **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.

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 physicians with electrode placement and stimulation programming. It has a series of touchscreens with a graphical user interface that provides information to the physician, such as measured data, test stimulation adjustments, and electrode configurations based on the utilization of proprietary algorithms. Further, it enables the clinician programmer to access any 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.

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

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

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

Our Bulkamid Product

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

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

The Bulkamid procedure is minimally invasive, with no cuts or incisions necessary, and typically takes around 10 to 15 minutes. It usually is performed in a physician's office or an outpatient facility 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 physician's office, hospital or clinic. Whilst experiencing no leakage at all is the most desired outcome of treatment, many women consider a successful treatment to be a meaningful decrease in the amount and frequency of urine leakage due to SUI such that they 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.

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

Over 90,000 women with stress urinary incontinence have been treated with Bulkamid across 25 countries over the last 16 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 sales worldwide. We have established a significant commercial infrastructure, with approximately 126 sales representatives in the United States. 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 who also have existing relationships with urologists and urogynecologists. We expect to focus the significant majority of our sales and marketing efforts in the United States where reimbursement for our therapies are well established and covered by 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.

In order to support our direct sales team, we have approximately 140 clinical specialists. This clinical staff is primarily responsible for attending SNM 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 and Bulkamid therapies for the treatment of OAB among patients and physicians, as well as awareness of the benefits and advantages of our products. We 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 or Bulkamid therapy. We may also engage in broad marketing initiatives in jurisdictions where we are permitted to do so.

Although our main commercial priority is the United States, in November 2018, we launched a limited commercial effort in Europe. With the addition of the Bulkamid international sales force, we currently have approximately 23 dedicated sales representatives and clinical specialists in the United Kingdom, Germany, Netherlands and the Nordic countries, with distributors serving certain other international markets around the world.

Third-Party Coverage and Reimbursement

In the United States, we derive revenue from the sale of our products to hospitals and ambulatory surgical centers, which typically bill various third-party payors, including Medicare, Medicaid, private insurance companies, health maintenance organizations and other healthcare-related organizations. In addition, we expect that any portion of the costs and fees associated with our 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. As SNM therapy has been widely used in patients for over 20 years in the United States, reimbursement codes and payments are well-established and the procedure is covered by Medicare, Medicaid and private health insurance plans. Similarly, urethral bulking agent treatment reimbursement codes and payments are well-established and the procedure is covered by Medicare, Medicaid and private health insurance plans.

Physician reimbursement under Medicare is generally based on a defined fee schedule (the Physician Fee Schedule), through which payment amounts are determined by the relative value of the service rendered by the physician. Medicare generally provides reimbursement to hospitals and ambulatory surgical centers for SNM therapy under the hospital outpatient prospective payment system and the Ambulatory Surgical Center Payment System, respectively, which reimburse to the hospital or ambulatory surgical center, as applicable, a bundled amount generally intended to cover all facility costs related to procedures performed in the outpatient setting. The typical Medicare payment for facility and physician services for an SNM trial and full system implant ranges from approximately $23,000 to approximately $27,000, 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 64561 for percutaneous 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 to expand our suite of products for SNM therapy. To that end, in late June 2021, we filed a PMA supplement with the FDA for a long-lived non-rechargeable SNM device that, among other things, utilizes a primary cell battery. Research and development expenses were approximately $37.3 million, $29.1 million, and $20.1 million for the years ended December 31, 2021, 2020, and 2019, respectively.

Manufacturing and Supply

We use a combination of in-house and outsourced vendors to manufacture various components of our products. 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 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 products under strict manufacturing processes supported by internal policies and procedures. We perform our own final quality control testing of each product. However, we do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with current Good Manufacturing Practice (cGMP) regulations applicable to our products.

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

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

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

Competition

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

We consider our primary competition to be implantable SNM devices offered by Medtronic. Medtronic's InterStim 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 bulking agent. In addition, emerging businesses may be in the early stages of developing additional products or therapies designed to treat OAB, FI or SUI.

Intellectual Property

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

We own numerous issued patents and pending patent applications that relate to our 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, 2021, we own 44 issued U.S. patents and 141 issued foreign patents, and 21 pending U.S. patent applications and 24 pending foreign patent applications. We also license from AMF 25 issued U.S. patents and three pending U.S. patent applications, as well as 50 issued foreign patents and six 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 licensed us the AMF IP relating to AMF Licensed Products.

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

anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) a minimum annual royalty (the Minimum Royalty), payable quarterly. The Minimum Royalty automatically increases each year, subject to a maximum amount of $200,000 per year. During the years ended December 31, 2021, 2020, and 2019, we have recorded royalties of $6.3 million, $4.4 million, and $0.6 million, respectively.

Government Regulation Applicable to Us

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, including the 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; 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.

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

Starting January 1, 2021, all medical devices sold in the United Kingdom must meet new regulatory requirements due to the U.K.'s departure from the 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 United Kingdom, it must appoint a U.K. Responsible Person to register with the MHRA and assist the company in meeting U.K. regulatory requirements.

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

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

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

Recognizing that the U.S. Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the 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.

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

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

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

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

Anti-Bribery and Corruption Laws

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

FCC Regulation

Because our 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, and, in certain circumstances, criminal penalties with fines and/or imprisonment.

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

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

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

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

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

Impact of COVID-19

The COVID-19 pandemic negatively impacted our sales in 2020 and 2021, by significantly decreasing and delaying the number of procedures performed using our r-SNM System, and we expect that the pandemic and related effects on elective procedures and hospital staffing shortages 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 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 through the second quarter of 2021. During the second half of 2021, certain outpatient elective procedures were again postponed or cancelled related to the COVID-19 pandemic and specifically the Delta and Omicron variants, which adversely affected our business during the second half of 2021.

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, 2021, we had 517 employees. Of this total, 23 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. In March 2021, we changed our name to Axonics, 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 $80.1 million, $54.9 million, and $79.9 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $314.6 million. To date, we have financed our operations primarily through equity financings.

We expect that our operating expenses will continue to increase as we (i) continue to expand our commercial infrastructure, (ii) develop, enhance, and expand the commercialization of our 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, and (iv) increase our commercialization efforts internationally. As a result, we expect to continue to incur operating losses for the foreseeable future. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

If we do not generate sufficient revenue, 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 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 hired and trained sales representatives and clinical specialists with strong backgrounds and experience in SNM therapy and other neurostimulation applications, and who have existing relationships with urologists and urogynecologists. However, we expect that our sales force will require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products will often require or benefit from direct support from us. If our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent any of our sales force is comprised of personnel hired from our competitor, we may have to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. This may subject us to allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Addressing such allegations would be costly both in terms of time and resources. Any of these risks may adversely affect our business.

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 our products in sufficient quantities in a timely manner. Our limited manufacturing history may not provide us with enough data to accurately predict future component demand, fluctuations in availability and pricing of commodity materials of supply, and, to anticipate our costs and supply needs effectively. We may in the future experience delays in obtaining components from suppliers, which could impede our ability to manufacture and assemble our products on our expected timeline. As a result of this or any other delays, we may encounter difficulties in production of our products, including problems with quality control and assurance, component supply shortages or surpluses (including with respect to the ceramic and titanium we use in our products), increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements.

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

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

Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth we will need to continue to improve our operational, compliance and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

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

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

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

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

We may need to raise additional capital, and if we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders’ rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our 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 International also subjects us to all of the risks related to Contura International's business, which are all generally beyond our control. Contura International's ability to perform its obligations under the Manufacturing and Supply Agreement is dependent on Contura International'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.

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 could 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.

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 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.

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. 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 may adversely affect our business, operating results and financial condition.

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

Based on our experience, complications from use of our 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. 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. Further, any decline in the amount payors are willing to reimburse our customers could make it difficult for our customers to adopt or continue using our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

Outside the United States, reimbursement levels vary significantly by country and by region, particularly based on whether the country or region at issue maintains a single-payor system. SNM therapy is eligible for reimbursement in Canada, Australia, and certain countries in the EU, such as Germany, France, and the United Kingdom. Annual healthcare budgets generally determine the number of SNM systems that will be paid for by the payor in these single-payor system countries and regions. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. We intend to work with payors to obtain coverage and reimbursement approval in countries and regions where it makes economic sense to do so, however, we may not obtain such coverage, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business internationally.

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

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

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

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

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

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

We bear the risk of warranty claims on our products.

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

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

We rely extensively on information technology systems to conduct our business. These systems affect, among other things, ordering and managing materials from suppliers, shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security, and other processes necessary to manage our business. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and

our business continuity plans do not effectively compensate on a timely basis, we may experience interruptions in our operations, which could have an adverse effect on our business. 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, earthquakes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

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 ASCs focus on COVID-19 and as patients postpone healthcare visits and treatments. 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 ASCs 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 ASC capacity could have a significant adverse effect on our business, financial condition and results of operations following the end of the pandemic. Additionally, even after it is deemed advisable to resume conducting elective procedures, some patients may elect not to undergo procedures or delay scheduling procedures to avoid traveling to healthcare facilities due to safety concerns.

While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19

pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could have a material adverse effect on our long-term business as hospitals curtail and reduce capital and overall spending. In addition, the current economic downturn is resulting in significant job losses and reductions in disposable income and if patients are unable to obtain or maintain health insurance policies, this may significantly impact their ability to pay for the procedures utilizing our 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.

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 cannot prevent a physician from using our products off-label when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those that may be approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

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

penalties, damages (including treble damages), fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

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

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

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

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

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

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

- we may be required to submit an IDE application to FDA, which must become effective prior to commencing human clinical studies, and the FDA may reject our IDE application and notify us that we may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies;

- regulators and/or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical study at a prospective or specific trial site for various reasons, including safety signals or noncompliance with regulatory requirements;
- we may not reach agreements with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- our third-party manufacturers, including those conducting clinical studies on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical study protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- the cost of clinical studies may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical study sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers or suppliers of materials for our clinical studies, the materials necessary to conduct clinical studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our products or other product candidates may have undesirable side effects or other unexpected characteristics.

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

Clinical studies must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with supplies of our product produced under cGMP requirements and other regulations. Furthermore, we rely on clinical study sites to ensure the proper and timely conduct of our clinical studies and we have limited influence over their performance. We depend on our collaborators and on medical

institutions and employees to conduct our clinical studies in compliance with good clinical practice (GCP) requirements. If our collaborators fail to enroll participants for our clinical studies, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical studies that are conducted in countries outside the United States may result in additional delays and expenses due to increased shipment costs, additional regulatory requirements and the engagement of non-U.S. resources, and may expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

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

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

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

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

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

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

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

The methods used in, and the facilities used for, the manufacture of our products must comply with the QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing,

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

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

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

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

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations.

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

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

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

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

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

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

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

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

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any

challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- HIPAA which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which requires reports annually to the DHHS Centers for Medicare and Medicaid Services (CMS) information related to payments and other transfers of value to physicians;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers; and
- state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of

statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

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

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

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

The EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, which are often more restrictive than those in the United States and which restrict transfers of personal data to the United States unless certain requirements are met. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices.

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

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

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

federal or other applicable authorities may curtail our manufacturers' use of these materials and interrupt their business operations which could adversely affect our business.

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

Because we manufacture or contract to manufacture a product that contains titanium, we may be required under rules promulgated by the SEC governing disclosure of the use of "conflict minerals" (tin, tungsten, tantalum and gold) to determine whether those minerals are necessary to the functionality or production of our 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.

We depend upon third-party suppliers, including single source component suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers, including some single source suppliers for certain components of our products, to provide us with a portion of our demand for one of our products as well as components used in the manufacturing of our products. In some cases, we purchase supplies through purchase orders and do not have long-term supply agreements with, or guaranteed commitments from, our component suppliers, including single source suppliers. Many of our suppliers and contract manufacturers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers to provide us and our customers with materials or products in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, including as a result of the ongoing COVID-19 pandemic, any of which could delay or impede their ability to meet our demand. These suppliers may cease producing the products or components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. In addition, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe alternate suppliers exist for all materials, components and services necessary to manufacture our products, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time-consuming, expensive and may result in interruptions in our operations and product delivery. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay or which may not be obtained at all. If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost, volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

For example, the COVID-19 pandemic has disrupted the operations of certain of our third-party suppliers, resulting in increased lead-times for our purchases of some components and, in certain cases, requiring us to procure materials from alternate suppliers or incur higher logistics expenses. We have worked closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand and have not experienced disruptions in our supply chain to date. However, there is no assurance that we will not experience more significant disruptions in our supply chain in the future, particularly if the operations of our contract manufacturing partners or any of our critical single source suppliers are more severely impacted by the pandemic and associated labor and component shortages. Any supply interruption from our suppliers or failure to obtain additional suppliers for products or any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Intellectual Property

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

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

Third parties may assert that we, or any of our current or future licensors, including AMF, are employing their proprietary technology without authorization. For example, on November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (collectively, the Medtronic Affiliates) filed a complaint against us in the 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. The USPTO issued decisions on the IPR petitions in September 2021. The USPTO invalidated several claims in the Medtronic patents but declined to invalidate the majority of asserted claims. We appealed the decisions on the claims that were not invalidated. Following these IPR decisions, the judge presiding over the litigation in the United States District Court for the Central District of California lifted the stay on litigation proceedings. We are currently engaged in discovery in the Medtronic Litigation.

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, 2021, we own 44 issued U.S. patents and 141 issued foreign patents, and 21 pending U.S. patent applications and 24 pending foreign patent applications. We also license from AMF 25 issued U.S. patents and three pending U.S. patent applications, as well as 50 issued foreign patents and six 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.

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.

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, in September 2020, the lease was amended to extend the expiration date to July 31, 2022, and in December 2021, the lease was amended to extend the expiration date to January 31, 2028.

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. We use 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 a 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. The USPTO issued decisions on the IPR petitions in September 2021. The USPTO invalidated several claims in the Medtronic patents but declined to invalidate the majority of asserted claims. We have appealed the decisions on the claims that were not invalidated. Following these IPR decisions, the judge presiding over the litigation in the United States District Court for the Central District of California lifted the stay on litigation proceedings. We are currently engaged in discovery in the Medtronic Litigation.

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, 2022, there were approximately 543 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

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

Unregistered Sales of Equity Securities

Except as previously disclosed in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, we had no sales of unregistered equity securities during fiscal year 2021.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Performance Graph

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

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

Item 6. [Reserved]

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 is developing and commercializing novel products for adults with bladder and bowel dysfunction, including: (i) implantable SNMs 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, with an additional 40 million adults estimated to suffer from FI. SUI affects an estimated 29 million women in the United States alone.

SNM therapy is an effective and durable treatment for UUI, UUF, UR and FI that has been widely used and reimbursed in Europe and the United States for the past two decades. Bulkamid is also an effective and durable treatment for SUI. Bulkamid was approved by the FDA for use in the United States in early 2020 and is widely reimbursed in the United States and most international markets.

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 U.S. SNM market is now approximately $750 million and believe it is a growing market. Until we entered the market, it was serviced by Medtronic as a single participant.

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

We have marketing approvals in the United States, Europe, Canada, and Australia for all relevant clinical indications and initiated limited commercial efforts in England, the Netherlands and Canada in late 2018 and subsequently in Germany and Switzerland. SNM revenue in 2021 from international operations in the Netherlands, England, Canada, Switzerland, and Germany, was approximately $3.8 million.

We are primarily focused on commercializing our products in the United States, which accounts for the vast majority of sales worldwide. We have established a significant commercial infrastructure, with approximately 290 sales and clinical support personnel in the United States. 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 who also have existing relationships with urologists and urogynecologists.

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

On February 25, 2021, we acquired 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 is sold through a combination of a direct sales force in the United States and certain European countries and distributors in certain international markets. The acquisition of Contura has expanded our international operations.

In May 2021, we received a CE Mark approval on our second-generation rechargeable INS and wireless patient remote control with SmartMRI™ technology.

In May 2021, the FDA approved the use of detachable extremity coils for patients undergoing 1.5T and 3.0T MRI scans.

In late June 2021, we filed a PMA supplement with the FDA for our newly developed, long-lived, non-rechargeable SNM system. The non-rechargeable INS will utilize a primary cell battery with an expected life of at least 10 years with standard stimulation parameters. The non-rechargeable INS submitted for FDA approval is approximately 10cc in volume, utilizes constant current stimulation and a recharge-free patient remote control, and is expected to be MRI compatible with 1.5T and 3.0T scanners.

Our ability to generate revenue and become profitable will depend on our ability to continue to successfully commercialize our products and any product enhancements we may advance in the future. We expect to derive future revenue by increasing patient and physician awareness of our products. 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.

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, particularly if that country maintains a single-payor system. SNM therapy is eligible for reimbursement in Canada, Australia, and certain countries in Europe, such as Germany 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.

We currently outsource the manufacture of certain implantable components of our r-SNM System. 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 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 spend a significant amount of our resources on sales and marketing activities to commercialize and market our r-SNM System in the United States.

We incurred net losses of $80.1 million, $54.9 million, and $79.9 million for the years ended December 31, 2021, 2020, and 2019, respectively, and had an accumulated deficit of $314.6 million as of December 31, 2021, compared to $234.5 million at December 31, 2020. As of December 31, 2021, we had available cash and cash equivalents of approximately $220.9 million, current liabilities of approximately $26.9 million, and long-term liabilities of approximately $38.6 million.

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.

May 2021 Follow-On Offering

On May 14, 2021, we completed a follow-on offering by issuing 4,025,000 shares of common stock, at an offering price of $50.00 per share, inclusive of 525,000 shares of 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 $201.3 million and the net proceeds were approximately $190.0 million, after deducting underwriting discounts, commissions and offering expenses payable by us.

Impact of COVID-19

The COVID-19 pandemic negatively impacted our sales, starting 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 through the second quarter of 2021. During the second half of 2021, certain outpatient elective procedures were again postponed or cancelled related to the COVID-19 pandemic and specifically the Delta and Omicron variants, which adversely affected our business during the second half of 2021.

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. Even as efforts to contain the pandemic have made progress and some restrictions have relaxed, new variants of the virus may continue to cause additional outbreaks. 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 licensed us the AMF IP relating to AMF Licensed Products.

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) 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, 2021, 2020, and 2019, we have recorded royalties of $6.3 million, $4.4 million, and $0.6 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 during the years ended December 31, 2021, 2020, and 2019 are as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
SNM net revenue			
United States	$ 153,837	$ 107,542	$ 8,376
International markets	3,753	3,993	5,444
	$ 157,590	$ 111,535	$ 13,820
Bulkamid net revenue			
United States	$ 12,660	$ —	$ —
International markets	10,040	—	—
	$ 22,700	$ —	$ —
Total net revenue	$ 180,290	$ 111,535	$ 13,820

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of costs of the components of our r-SNM System, third-party contract labor costs, overhead costs, Bulkamid product costs, as well as distribution-related expenses such as logistics and shipping costs. The overhead costs include the cost of material procurement and operations supervision and management personnel. We expect overhead costs as a percentage of 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 manufacturing costs, 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 products, 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, royalty expense, and clinical studies to develop and support our r-SNM System, including clinical study and registry management and monitoring, payments to clinical investigators, and data management. Other research and development expenses include consulting and advisory fees, royalty expense, travel expenses, and equipment-related expenses and other miscellaneous office and facilities expenses related to research and development programs. Research and development costs are expensed as incurred. We expect to continue incurring research and development expenses in the future as we develop 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, 2021, 2020, and 2019 (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Personnel related	$ 19,192	$ 12,176	$ 11,917
Clinical development	862	501	1,401
Contract R&D and manufacturing	9,960	10,548	4,936
Royalty expense	6,282	4,421	553
Other R&D expenses	1,001	1,409	1,259
Total R&D expenses	$ 37,297	$ 29,055	$ 20,066

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, changes in fair value of the contingent consideration, 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 additional 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 sales personnel commissions and stock-based compensation, trade shows, booth exhibition costs, and the related travel for these events. Other sales and marketing expenses include direct-to-consumer promotional programs, 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.

Amortization of Intangible Assets

Amortization of intangible assets consist primarily of amortization expense on patent license asset, manufacturing license asset, technology, and customer relationships. We amortize finite lived intangible assets over the period of estimated benefit using the straight-line method. Indefinite lived intangible assets are tested for impairment annually or whenever events or circumstances indicate that the carrying amount of the asset (asset group) may not be recoverable. If impairment is indicated, we measure the amount of the impairment loss as the amount by which the carrying amount exceeds the fair value of the asset. Fair value is generally determined using a discounted future cash flow analysis.

Acquisition-Related Costs

Acquisition-related costs consist of expenses incurred related to the Contura acquisition.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest expense payable under the Loan Agreement with Silicon Valley Bank and other debt arrangements, gains and losses on foreign currency transactions, net of interest income earned on cash equivalents.

Income Tax Expense

Income tax expense primarily consists of a remeasurement of deferred tax liabilities in our foreign operations as a result of a change in enacted tax rates in the U.K., net of losses benefited in certain foreign jurisdictions. We maintain a full valuation allowance for deferred tax assets in our domestic operations, including net operating loss carryforwards and research and development credits.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table shows our results of operations for the years ended December 31, 2021 and 2020 (in thousands, except percentages):

	Years Ended December 31,		Period to Period Change
	2021	2020	
Net revenue	$ 180,290	$ 111,535	$ 68,755
Cost of goods sold	64,572	44,444	20,128
Gross profit	115,718	67,091	48,627
Gross Margin	*64.2 %*	*60.2 %*	
Operating expenses			
Research and development	37,297	29,055	8,242
General and administrative	32,785	25,551	7,234
Sales and marketing	105,789	66,130	39,659
Amortization of intangible assets	7,241	115	7,126
Acquisition-related costs	4,414	—	4,414
Total operating expenses	187,526	120,851	66,675
Loss from operations	(71,808)	(53,760)	(18,048)
Other income (expense)			
Interest income	40	761	(721)
Loss on disposal of property and equipment	(91)	(41)	(50)
Interest and other expense	(7,426)	(1,874)	(5,552)
Other expense, net	(7,477)	(1,154)	(6,323)
Loss before income tax expense	(79,285)	(54,914)	(24,371)
Income tax expense	782	1	781
Net loss	(80,067)	(54,915)	(25,152)
Foreign currency translation adjustment	(6,129)	(3)	(6,126)
Comprehensive loss	$ (86,196)	$ (54,918)	$ (31,278)

Net Revenue

Net revenue was $180.3 million in fiscal year 2021 and was primarily derived from the sale of our products to customers in the United States and certain international markets. Net revenue was $111.5 million in fiscal year 2020 and was primarily derived from the sale of our r-SNM System to customers in the United States, Europe and Canada. The increase in net revenue is primarily due to increased sales of our r-SNM System as we expanded our customer base in the U.S. and international markets and the addition of $22.7 million in Bulkamid sales. Sales in fiscal year 2020 were also more severely impacted by the COVID-19 global pandemic, with the initial restrictions on elective procedures occurring during the second quarter of 2020 and continuing through 2021.

Cost of Goods Sold and Gross Margin

We incurred $64.6 million of cost of goods sold in fiscal year 2021. We incurred $44.4 million in fiscal year 2020. Gross margin was 64.2% in fiscal year 2021, compared to 60.2% in fiscal year 2020. The increase in gross margin is primarily due to increased efficiencies resulting in higher absorption rates.

Research and Development Expenses

Research and development expenses increased $8.2 million, or 28.4%, to $37.3 million in fiscal year 2021, compared to $29.1 million in fiscal year 2020. The increase in research and development expenses was primarily attributable to an increase of $7.0 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits.

General and Administrative Expenses

General and administrative expenses increased $7.2 million, or 28.4%, to $32.8 million in fiscal year 2021, compared to $25.6 million in fiscal year 2020, primarily as a result of an increase of $3.6 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits and an increase of $2.7 million in the change in fair value of the contingent consideration.

Sales and Marketing Expenses

Sales and marketing expenses increased $39.7 million, or 60.0%, to $105.8 million in fiscal year 2021, compared to $66.1 million in fiscal year 2020. The increase in sales and marketing expenses was primarily due to an increase of $27.4 million related to personnel costs including salaries, wages, sales personnel commissions, stock-based compensation and other employee-related benefits, an increase of $4.9 million related to direct-to-consumer programs and other advertising expenses, and an increase of $3.5 million related to travel expenses.

Amortization of Intangible Assets

Amortization of intangible assets increased to $7.2 million in fiscal year 2021, compared to $0.1 million in fiscal year 2020. The increase in amortization of intangible assets was primarily due to an increase of technology and customer relationships acquired related to the Contura acquisition.

Acquisition-Related Costs

Acquisition-related costs was $4.4 million in fiscal year 2021 related to the Contura acquisition.

Other Expense, Net

Other expense, net was $7.5 million in fiscal year 2021, consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank. 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.

Income Tax Expense

Income tax expense was $0.8 million in fiscal year 2021 primarily related to the remeasurement of our U.K. deferred tax liabilities due to an increase in the U.K. income tax rate, net of losses benefited in certain foreign jurisdictions. We recorded minimal income tax expense in fiscal year 2020.

Comparison of the Years Ended December 31, 2020 and 2019

For a comparison of our results of operations and cash flows for the years ended December 31, 2020 and 2019, see “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our annual report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 1, 2021.

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 $80.1 million, $54.9 million, and $79.9 million for the years ended December 31, 2021, 2020, and 2019, respectively, and had an accumulated deficit of $314.6 million as of December 31, 2021 compared to $234.5 million at December 31, 2020. 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, 2021, we had cash and cash equivalents of $220.9 million compared to $241.2 million at December 31, 2020. We expect that our cash and cash equivalents on hand will be sufficient to fund our operations through at least the next 12 months. We fund our operations through a combination of proceeds from public offerings of our common stock and cash receipts from sales of our products. As of December 31, 2021, we had no outstanding borrowings.

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, 2021, 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]	$ 12,892	$ 2,063	$ 4,160	$ 4,389	$ 2,280
Purchase Obligations[2]	38,618	38,618	—	—	—
Other Long-Term Liabilities[3]	2,375	175	400	400	1,400
Total	$ 53,885	$ 40,856	$ 4,560	$ 4,789	$ 3,680

(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 January 31, 2028.

(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.

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

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

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

Cash Flows

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

	Years Ended December 31,		
	2021	2020	2019
Net cash provided by (used in)			
Operating activities	$ (47,306)	$ (83,742)	$ (83,454)
Investing activities	(143,002)	9,654	45,287
Financing activities	170,513	144,190	110,955
Effect of exchange rate changes on cash and cash equivalents	(508)	(3)	(12)
Net (decrease) increase in cash and cash equivalents	$ (20,303)	$ 70,099	$ 72,776

Net cash used in operating activities

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

Net cash used in 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) provided by investing activities

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

Net cash 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.

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 provided by financing activities

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

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 May 2020 follow-on offering.

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.

Indebtedness

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

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

We have no further indebtedness arrangements.

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, 2021, 2020, and 2019 relates entirely to the sale of our products to our customers and distributors.

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 also sell to distributors and apply the same policies as our revenue arrangements with customers, specifically that revenue is recognized at the point in time when we transfer control of promised goods to our distributors, revenue is measured as the amount of consideration we expect 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, do not include a significant financing component. We extend credit to our customers and distributors based upon an evaluation of their 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 and distributors are included in cost of goods sold. Amounts billed to customers and distributors for shipping and handling are included in net revenue.

Allowance for Credit Losses

We make estimates of the collectability of accounts receivable in accordance with ASU 2016-13. 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, customers 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 customers are highly uncertain and cannot be predicted. As a result, our future collection experience can differ significantly from historical collection trends. If our customers 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.

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

Contingent consideration represents contingent milestone, performance and revenue-sharing payment obligations related to acquisitions and is measured at fair value, based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration is estimated using a binary option-based approach with assumptions we believe would be made by a market participant. Significant inputs include projected revenues, discount rates, volatility factors and risk-free rates. We assess these assumptions on an ongoing basis as additional data impacting the assumptions is obtained and any change in fair value of the contingent consideration is recorded in the consolidated statements of comprehensive loss. Significant increases or decreases in any of those inputs in isolation would result in a significantly lower or higher fair value measurement. Generally, a change in the assumption used for the projected revenues would result in a directionally similar change to the overall estimate of the contingent consideration.

Investment Securities

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. Revenue and expenses of the subsidiaries are translated into U.S. dollars at the average

exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' equity in accumulated other comprehensive gain or loss until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss).

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 may also be used in clinical programs to assess the safety and efficacy of the products for usage that have not been approved by the FDA or other regulatory authorities. The form of product utilized for both commercial and certain clinical programs that are identical are included as inventory with an "alternative future use" as defined in 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. Our products currently have 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 inventory costs will be realizable or not 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.

Goodwill

Goodwill represents the excess purchase price over the fair values of the identifiable assets acquired less the liabilities assumed. Goodwill is tested for impairment at the reporting unit level by comparing the reporting unit's carrying amount to the fair value of the reporting unit. The fair values are estimated using an income and discounted cash flow approach. We evaluate our goodwill on an annual basis in the fourth quarter or more frequently if we believe indicators of impairment exist. We assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount or perform an annual impairment test. When tested quantitatively, we compare the fair value of the applicable reporting unit with its carrying value. In making this assessment, management relies on a number of factors, including expected future operating results, business plans, economic projections, anticipated future cash flows, business trends and declines in our market capitalization. We estimate the fair values of our reporting unit using a combination of the discounted cash flow

(DCF) and income approaches. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the amount by which the carrying value exceeds the fair value is recognized as an impairment loss.

Intangible Assets

Patent license asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The additional field-of-use was provided in exchange for 50,000 shares of Series A preferred stock, the fair value of which was $1.0 million in 2013. The intangible asset was recorded at its fair value of $1.0 million at the date contributed. In connection with 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.

Exclusive license asset

The intangible asset represents exclusive rights of existing technologies and development services from MST entered into on March 2, 2021. The agreement was provided in exchange for 65,594 shares of common stock, $0.0001 par value, the fair value of which was $3.6 million upon transfer. The intangible asset was recorded at its fair value of $3.3 million at the date of the agreement, with the difference of $0.3 million recorded as a vendor credit in accounts payable in the consolidated balance sheets. Amortization of this asset is recorded over the four-year term of the agreement on a straight-line basis. We will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date.

Contura acquisition

The intangible assets represent technology, trade names and trademarks, and customer relationships acquired from Contura on February 25, 2021. The straight-line method over the period of estimated benefit is used to amortize finite-lived intangible assets except for customer relationships. Accounting Standards Codification (ASC) 350-30-35-3 states that customer relationships generally dissipate at a more rapid rate in the earlier periods following a company's succession to these relationships, with the rate of attrition declining over time. As such, the accelerated method is used to amortize customer relationships.

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 minimal impairments of long-lived assets to date.

Leases

In accordance with Accounting Standards Update (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 between operating and finance leases. 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 leases do 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 net deferred tax assets in certain jurisdictions. 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 U.S. net 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 Disclosures About Market Risk.

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

Interest Rate Risk

We had cash and cash equivalents of $220.9 million as of December 31, 2021, which came from public offerings of our common stock and cash receipts from our product sales. The goals of our investment policy are liquidity and capital preservation and we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash and cash equivalents. 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, Inc.
Irvine, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Axonics, Inc. (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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, 2022 expressed an adverse opinion thereon.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Accounting for an Acquisition

As described in Note 9 to the consolidated financial statements, the Company completed the acquisition of Contura Limited for the purchase price of approximately $204.7 million during the year ended December 31, 2021. As a result of this business combination, the Company recorded $112.2 million of identifiable intangible assets and $7.6 million in contingent consideration.

We identified management's judgements used to determine the fair values of identifiable intangible assets and the contingent consideration related to the Contura Limited acquisition as a critical audit matter. The principal considerations for our determination are the subjective judgement required by management in formulating forecasted revenues and assessing the appropriateness of the valuation methodologies and the discount, royalty and attrition rates used in developing the fair values of the acquired identifiable intangible assets and the contingent consideration.

Auditing these considerations involved especially subjective and challenging auditor judgement 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:

- Assessing the reasonableness of forecasted revenue by comparing to historical performance and evaluating significant inputs used in the development of forecasted revenue.
- Utilizing personnel with specialized knowledge and skill in valuation to assist in: (i) assessing the appropriateness of the valuation methodologies, (ii) evaluating the reasonableness of certain significant assumptions including discount, royalty, and attrition rates used in the valuation models and (iii) evaluating the potential effect of changes in certain critical assumptions on the fair value calculations.

/s/ BDO USA, LLP

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

Costa Mesa, California
March 1, 2022

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

	December 31,	
	2021	**2020**
ASSETS		
Current assets		
Cash and cash equivalents	$ 220,878	$ 241,181
Accounts receivable, net of allowance for credit losses of $355 and $465 at December 31, 2021 and 2020, respectively	29,044	18,270
Inventory, net	64,946	63,060
Prepaid expenses and other current assets	6,449	5,435
Total current assets	321,317	327,946
Property and equipment, net	6,915	6,328
Intangible assets, net	106,469	196
Other assets	7,734	7,736
Goodwill	105,510	—
Total assets	$ 547,945	$ 342,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 7,654	$ 10,660
Accrued liabilities	5,435	6,684
Accrued compensation and benefits	12,413	5,948
Operating lease liability, current portion	1,366	1,280
Debt, net of unamortized debt issuance costs, current portion	—	21,110
Total current liabilities	26,868	45,682
Operating lease liability, net of current portion	9,052	9,154
Deferred tax liabilities, net	19,217	—
Other long-term liabilities	10,370	—
Total liabilities	65,507	54,836
Commitments and contingencies (Note 4)		
Stockholders' equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, par value $0.0001 per share, 50,000,000 shares authorized at December 31, 2021 and 2020; 46,330,167 and 39,931,030 shares issued and outstanding at December 31, 2021 and 2020, respectively	5	4
Additional paid-in capital	803,559	522,296
Accumulated deficit	(314,566)	(234,499)
Accumulated other comprehensive loss	(6,560)	(431)
Total stockholders' equity	482,438	287,370
Total liabilities and stockholders' equity	$ 547,945	$ 342,206

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2021	**2020**	**2019**
Net revenue	$ 180,290	$ 111,535	$ 13,820
Cost of goods sold	64,572	44,444	6,490
Gross profit	115,718	67,091	7,330
Operating expenses			
Research and development	37,297	29,055	20,066
General and administrative	32,785	25,551	19,076
Sales and marketing	105,789	66,130	48,672
Amortization of intangible assets	7,241	115	115
Acquisition-related costs	4,414	—	—
Total operating expenses	187,526	120,851	87,929
Loss from operations	(71,808)	(53,760)	(80,599)
Other income (expense)			
Interest income	40	761	2,974
Loss on disposal of property and equipment	(91)	(41)	—
Interest and other expense	(7,426)	(1,874)	(2,309)
Other (expense) income, net	(7,477)	(1,154)	665
Loss before income tax expense	(79,285)	(54,914)	(79,934)
Income tax expense	782	1	1
Net loss	(80,067)	(54,915)	(79,935)
Foreign currency translation adjustment	(6,129)	(3)	(12)
Comprehensive loss	$ (86,196)	$ (54,918)	$ (79,947)
Net loss per share, basic and diluted (see Note 1)	$ (1.86)	$ (1.48)	$ (2.80)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	43,072,298	36,981,335	28,567,302

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance at December 31, 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 offering 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 offering 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
Issuance of common stock for employee stock option exercises for cash	522,495	—	6,757	—	—	6,757
RSA issuances and forfeitures for terminations, net and stock-based compensation	520,411	—	17,793	—	—	17,793
Issuance of common stock for vesting of RSU and stock-based compensation	169,054	—	7,371	—	—	7,371
Follow-on offering - issuance of 4,025,000 shares at $50.00 per share, less offering costs of $11,272	4,025,000	1	189,977	—	—	189,978
Issuance of common stock for acquisition of Contura Limited	1,096,583	—	55,728	—	—	55,728
Issuance of common stock for exclusive license asset	65,594	—	3,637	—	—	3,637
Foreign currency translation adjustment	—	—	—	—	(6,129)	(6,129)
Net loss	—	—	—	(80,067)	—	(80,067)
Balance at December 31, 2021	46,330,167	$ 5	$ 803,559	$ (314,566)	$ (6,560)	$ 482,438

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2021	**2020**	**2019**
Cash Flows from Operating Activities			
Net loss	$ (80,067)	$ (54,915)	$ (79,935)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	9,126	1,741	1,191
Loss on disposal of property and equipment	91	41	—
Stock-based compensation	25,164	15,095	8,720
Amortization of debt issuance costs	4,991	774	873
(Reversal of) provision for allowance of credit losses	(122)	390	75
Change in fair value of contingent consideration	2,740	—	—
Deferred income taxes and other items, net	582	165	—
Changes in operating assets and liabilities, net of business acquisition			
Accounts receivable	(8,998)	(10,781)	(7,527)
Inventory	(1,108)	(47,353)	(11,986)
Prepaid expenses and other current assets	(940)	(863)	(752)
Other assets	(225)	(90)	(299)
Accounts payable	(2,862)	4,778	2,446
Accrued liabilities	(1,976)	4,193	1,155
Accrued compensation and benefits	6,155	2,573	2,711
Lease liability	143	510	(126)
Net cash used in operating activities	(47,306)	(83,742)	(83,454)
Cash Flows from Investing Activities			
Purchases of property and equipment	(2,261)	(2,938)	(1,339)
Acquisition of a business, net of cash acquired	(140,741)	—	—
Purchases of short-term investments	—	—	(36,404)
Proceeds from sales and maturities of short-term investments	—	12,592	83,030
Net cash (used in) provided by investing activities	(143,002)	9,654	45,287
Cash Flows from Financing Activities			
Payment of debt issuance costs	(106)	—	—
Proceeds from debt	75,000	—	—
Repayment of debt	(101,116)	—	—
Proceeds from offering of common stock upon follow-on public offering	201,250	149,500	117,590
Payment of common stock offering costs upon follow-on public offering	(11,272)	(9,013)	(7,141)
Proceeds from exercise of stock options	6,757	3,703	506
Net cash provided by financing activities	170,513	144,190	110,955
Effect of exchange rate changes on cash and cash equivalents	(508)	(3)	(12)
Net (decrease) increase in cash and cash equivalents	(20,303)	70,099	72,776
Cash and cash equivalents, beginning of year	241,181	171,082	98,306
Cash and cash equivalents, end of year	$ 220,878	$ 241,181	$ 171,082
Supplemental Disclosure of Cash Flow Information			
Cash paid for interest	$ 2,178	$ 1,102	$ 1,436
Cash paid for taxes	$ 1	$ 1	$ 1
Noncash Investing and Financing Activities			
Common stock issuance for business acquisition	$ 55,728	$ —	$ —
Contingent consideration for business acquisition	$ 7,630	$ —	$ —
Common stock issuance for exclusive license asset	$ 3,637	$ —	$ —
Accrued loan fees as debt issuance costs	$ 4,500	$ —	$ —

See accompanying notes to consolidated financial statements.

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

Nature of Operations

Axonics, Inc. (the Company) was incorporated in the state of Delaware on March 2, 2012 under the name American Restorative Medicine, Inc. In August 2013, the Company changed its name to Axonics Modulation Technologies, Inc. In March 2021, the Company changed its name to Axonics, Inc. The Company 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 develops and commercializes innovative and minimally invasive products to treat bladder and bowel dysfunction. 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 had 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. Beginning in February 2021 with the acquisition of Contura Limited, the Company also markets Bulkamid, a urethral bulking agent to treat female stress urinary incontinence (SUI). For more information, see Note 9.

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.

May 2021 Follow-On Offering

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

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, Axonics Modulation

Technologies Australia Pty Ltd, Axonics Women's Health Limited, Bulkamid SARL, Axonics GmbH, and Contura, Inc. Intercompany accounts and transactions have been eliminated in consolidation.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). Certain prior year reported amounts have been reclassified to conform with the 2021 presentation.

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 and resurgence periods 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 again in the future that it is deemed advisable for health care facilities to not perform outpatient elective procedures, as was the case at various times throughout 2020 and 2021, the Company expects it would materially harm the Company's revenues and potentially increase the Company's operating loss. Even as efforts to contain the pandemic have made progress and some restrictions have relaxed, new variants of the virus may continue to cause additional outbreaks. 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 and such differences may be material to the consolidated financial statements.

Revenue Recognition

Revenue recognized during the years ended December 31, 2021, 2020, and 2019 relates entirely to the sale of the Company's products to its customers and distributors.

The Company has revenue arrangements that consist of a single performance obligation. The Company recognizes revenue at the point in time when it transfers control of promised goods to its customers. Revenue is measured as the amount of consideration 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 also sells to distributors and applies the same policies as its revenue arrangements with customers, specifically that revenue is recognized at the point in time when it transfers control of promised goods to its distributors, 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, do not include a significant financing component. The Company extends credit to its customers and distributors based upon an evaluation of their financial condition and credit history and generally requires no collateral. The Company does not have any contract balances related to product sales. The Company also does not have significant contract acquisition costs related to product sales.

In accordance with Company policy and based on the Company's historical experience, the allowance for product returns was $0.2 million and $0.3 million at December 31, 2021 and 2020, respectively. Damaged or defective products are replaced at no charge under the Company's standard warranty. For the years ended December 31, 2021, 2020, and 2019, the replacement costs were $0.2 million, $0.1 million, and minimal, respectively.

The Company offers its standard warranty to all customers. The Company does not sell any warranties on a standalone basis. The Company's warranty provides that its products are free of material defects and conform to specifications, and includes an offer to repair, replace or refund the purchase price of defective products. This assurance does not constitute a service and is not considered a separate performance obligation. The Company estimates warranty liabilities at the time of revenue recognition and records it as a charge to operating expenses. The warranty liability as of December 31, 2021 and 2020 were $0.1 million and $0.1 million, respectively.

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

The following table provides additional information pertaining to net revenue disaggregated by product and geographic market for the years ended December 31, 2021, 2020, and 2019 (in thousands):

	Years Ended December 31,		
	2021	**2020**	**2019**
SNM net revenue			
United States	$ 153,837	$ 107,542	$ 8,376
International markets	3,753	3,993	5,444
	$ 157,590	$ 111,535	$ 13,820
Bulkamid net revenue			
United States	$ 12,660	$ —	$ —
International markets	10,040	—	—
	$ 22,700	$ —	$ —
Total net revenue	$ 180,290	$ 111,535	$ 13,820

Allowance for Credit Losses

The Company makes estimates of the collectability of accounts receivable in accordance with ASU 2016-13. 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, customers 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 customers 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 customers experience a negative impact on their cash flows, it could have a material adverse effect on the Company's results of operations and financial condition.

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

	Years Ended December 31,		
	2021	2020	2019
Balance at beginning of period	$ 465	$ 75	$ —
Write-offs	12	—	—
Bad debt (recoveries) expense	(122)	390	75
Balance at end of period	$ 355	$ 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.

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

Contingent consideration represents contingent milestone, performance and revenue-sharing payment obligations related to acquisitions and is measured at fair value, based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration is estimated using a binary option-based approach with assumptions the Company believes would be made by a market participant. Significant inputs include projected revenues, discount rates, volatility factors and risk-free rates. The Company assesses these assumptions on an ongoing basis as additional data impacting the assumptions is obtained and any change in fair value of the contingent consideration is recorded in the consolidated

statements of comprehensive loss. Significant increases or decreases in any of those inputs in isolation would result in a significantly lower or higher fair value measurement. Generally, a change in the assumption used for the projected revenues would result in a directionally similar change to the overall estimate of the contingent consideration. The fair value of contingent consideration of $10.4 million at December 31, 2021 is reflected in other long-term liabilities on the Company's consolidated balance sheets with the change in fair value of $2.7 million during the year ended December 31, 2021 reflected in general and administrative expenses in the consolidated statements of comprehensive loss.

The following table summarizes the changes in the fair value of recurring Level 3 fair value measurements during the year ended December 31, 2021 (in thousands):

Liabilities		
Contingent consideration:		
December 31, 2020	$	—
February 25, 2021 Acquisition		7,630
Change in fair value included in earnings		2,740
December 31, 2021	$	10,370

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

Investment Securities

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, 2021, 2020, and 2019.

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, 2021 and 2020.

Foreign Currency Translation

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Revenue and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' equity in accumulated other comprehensive gain or loss until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss). As of December 31, 2021 and 2020, 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, 2021 and 2020.

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 may also be used in clinical programs to assess the safety and efficacy of the products for usage that have not been approved by the FDA or other regulatory authorities. The form of product utilized for both commercial and certain clinical programs that are identical are included as inventory with an "alternative future use" as defined in 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 Company's products currently have a maximum estimated shelf-life range of 12 to 36 months and based on sales forecasts, the Company expects to realize the carrying value of the product inventory. In the future, reduced demand, quality issues, or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

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

As of December 31, 2021, the Company had $46.8 million, $2.8 million, and $15.3 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, net of reserves of $0.2 million. 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. Reserves were de minimis as of December 31, 2020.

Customer and Vendor Concentration

As of December 31, 2021 and 2020, there were no customers who accounted for over 10% of the Company's consolidated accounts receivable. As of December 31, 2021 and 2020, there was no vendor and one vendor, respectively, who accounted for over 10% of the Company's consolidated accounts payable. As of December 31, 2021, 2020, and 2019, there were no customers who accounted for over 10% of the Company's consolidated net revenue. As of December 31, 2021, 2020, and 2019, there were three, two, and three vendors, respectively, who accounted for over 10% of the Company's inventory-related purchases.

Property and Equipment

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

Goodwill

Goodwill represents the excess purchase price over the fair values of the identifiable assets acquired less the liabilities assumed. Goodwill is tested for impairment at the reporting unit level by comparing the reporting unit's carrying amount to the fair value of the reporting unit. The fair values are estimated using an income and discounted cash flow approach. The Company evaluates its goodwill on an annual basis in the fourth quarter or more frequently if it believes indicators of impairment exist. The Company assesses qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount or performs an annual impairment test. When tested quantitatively, the Company compares the fair value of the applicable reporting unit with its carrying value. In making this assessment, management relies on a number of factors, including expected future operating results, business plans, economic projections, anticipated future cash flows, business trends and declines in the Company's market capitalization. The Company estimates the fair values of its reporting unit using a combination of the discounted cash flow (DCF) and income approaches. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the amount by which the carrying value exceeds the fair value is recognized as an impairment loss. During the year ended December 31, 2021, the Company did not record any impairment charges related to goodwill.

Intangible Assets

Patent license asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The additional field-of-use was provided in exchange for 50,000 shares of Series A preferred stock, the fair value of which was $1.0 million in 2013. The intangible asset was recorded at its fair value of $1.0 million at the date contributed. In connection with the 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. For additional information, see Note 3.

Exclusive license asset

The intangible asset represents exclusive rights of existing technologies and development services from MST entered into on March 2, 2021. The agreement was provided in exchange for 65,594 shares of common stock, $0.0001 par value, the fair value of which was $3.6 million upon transfer. The intangible asset was recorded at its fair value of $3.3 million at the date of the agreement, with the difference of $0.3 million recorded as a vendor credit in accounts payable in the consolidated balance sheets. Amortization of this asset is recorded over the four-year term of the agreement on a straight-line basis. The Company will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date. For additional information, see Note 3.

Contura acquisition

The intangible assets represent technology, trade names and trademarks, and customer relationships acquired from Contura on February 25, 2021. The straight-line method over the period of estimated benefit is used to amortize finite-lived intangible assets except for customer relationships. Accounting Standards Codification (ASC) 350-30-35-3 states that customer relationships generally dissipate at a more rapid rate in the earlier periods following a company's succession to these relationships, with the rate of attrition declining over time. As such, the accelerated method is used to amortize customer relationships. For additional information, see Notes 3 and 9.

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 minimal impairments of long-lived assets to date.

Leases

In accordance with Accounting Standards Update (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 between operating and finance leases. 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 leases do not provide an implicit rate, the Company uses its incremental borrowing rate, which is the rate for a fully collateralized amortizing loan with the same maturity as the lease term, 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, 2021, 2020, and 2019, advertising expense totaled $7.8 million, $2.9 million and $2.6 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 net deferred tax assets in certain jurisdictions. The realization of these deferred tax assets is dependent upon the Company's ability to generate sufficient taxable income in future years. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. The Company evaluates the recoverability of the deferred tax assets annually and maintains a full valuation allowance on its U.S. net deferred tax assets. 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, 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, 2021, 2020, and 2019, there were 2,444,444, 2,300,982, and 1,737,430 potentially dilutive weighted-average shares, respectively, that were not included in the computation of diluted weighted-average shares of common stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss.

Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined it operates in one segment, the development and

commercialization of innovative and minimally invasive products to treat bladder and bowel dysfunction. Geographically, the Company sells over 90% to hospitals in the United States. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (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 was the Company's first quarter of fiscal year 2021, with early adoption permitted. The adoption of this guidance did not have an impact on the Company's consolidated financial statements or related disclosures.

Recent Accounting Pronouncements

We have reviewed and considered all recent accounting pronouncements that have not yet been adopted and believe there are none that could potentially have a material impact on our business practices, financial condition, results of operations, or disclosures.

Note 2. Property and Equipment

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

	December 31,	
	2021	**2020**
Equipment	$ 2,429	$ 1,205
Computer hardware and software	2,450	2,286
Tools and molds	1,579	1,404
Leasehold improvements	4,372	3,759
Furniture and fixtures	1,502	1,360
Construction in progress	127	129
	12,459	10,143
Less: accumulated depreciation and amortization	(5,544)	(3,815)
	$ 6,915	$ 6,328

Depreciation and amortization expense of property and equipment was $1.9 million, $1.6 million, and $1.1 million for the years ended December 31, 2021, 2020, and 2019, respectively.

Note 3. Goodwill and Intangible Assets

The change in the carrying amount of goodwill during the year ended December 31, 2021 included the following (in thousands):

December 31, 2020	$ —
February 25, 2021 Acquisition	109,786
Foreign currency translation adjustment	(4,276)
December 31, 2021	$ 105,510

Intangible assets as of December 31, 2021 included the following (in thousands):

		December 31, 2021			
	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Foreign currency translation adjustment	Intangible Assets, Net
Patent license asset	8.71 years	$ 1,000	(919)	—	$ 81
Exclusive license asset	4 years	3,300	(660)	—	2,640
Technology	12 years	81,100	(5,668)	(1,424)	74,008
Trade names and trademarks	Indefinite	19,700	—	(365)	19,335
Customer relationships	12 years	11,400	(799)	(196)	10,405
		$ 116,500	$ (8,046)	$ (1,985)	$ 106,469

Intangible asset as of December 31, 2020 included the following (in thousands):

		December 31, 2020			
	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Foreign currency translation adjustment	Intangible Asset, Net
Patent license asset	8.71 years	$ 1,000	(804)	—	$ 196

The Company recorded expense for the amortization of intangible assets of $7.2 million, $0.1 million, and $0.1 million, respectively, during the years ended December 31, 2021, 2020, and 2019. The estimated future amortization expense as of December 31, 2021, is as follows (in thousands):

2022	$ 9,326
2023	9,138
2024	9,011
2025	7,970
2026	7,820

Note 4. Commitments and Contingencies

Operating Leases

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

During the years ended December 31, 2021, 2020, and 2019, ROU assets obtained in exchange for new operating lease liabilities were $1.0 million, $3.8 million, and $1.5 million, respectively. As of December 31, 2021 and 2020, the ROU asset has a balance of $7.1 million and $7.1 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, 2021, 2020, and 2019, cash paid for amounts included in operating lease liabilities were $2.0 million, $1.5 million, and $0.9 million, respectively. Amortization of the ROU asset was $1.0 million, $0.9 million, and $0.4 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021 and 2020, the weighted-average remaining lease term for the Company's operating leases were 5.9 years and 6.6 years, respectively. The weighted-average discount rate used to determine the present value of the Company's operating leases' future payments was 7.1% and 6.7%, respectively.

Total lease cost for the years ended December 31, 2021, 2020, and 2019 are as follows (in thousands):

	December 31,		
	2021	2020	2019
Lease cost			
Operating lease cost	$ 2,107	$ 1,991	$ 1,031
Short-term lease cost	95	95	177
Variable lease cost	191	179	138
Total lease cost	$ 2,393	$ 2,265	$ 1,346

Payments of operating lease liabilities as of December 31, 2021, are as follows (in thousands):

2022	$ 2,063
2023	2,094
2024	2,066
2025	2,150
2026	2,239
Thereafter	2,280
	12,892
Less: imputed interest	(2,474)
	10,418
Less: operating lease liability, current portion	(1,366)
Operating lease liability, net of current portion	$ 9,052

License Agreement

In October 2013, the Company entered into the License Agreement, pursuant to which AMF, a Company stockholder, licensed the Company certain patents and know-how (collectively, the AMF IP) relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (collectively, the AMF Licensed Products). Under the License Agreement, for each calendar year beginning in 2018, the Company is obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to the Company by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) the Minimum Royalty, payable quarterly. The Minimum Royalty automatically increases each year after 2018, subject to a maximum amount of $200,000 per year. The Company generated net SNM revenue of $157.6 million, $111.5 million, and $13.8 million during the years ended December 31, 2021, 2020, and 2019, respectively, and recorded related royalties of $6.3 million, $4.4 million, and $0.6 million during the years ended December 31, 2021, 2020, and 2019, respectively. Royalty expense is included in operating expenses in the consolidated statements of comprehensive loss. Accrued royalty of $1.8 million and $1.4 million as of December 31, 2021 and 2020, 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 a 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 USPTO issued decisions on the IPR petitions in September 2021. The USPTO invalidated several claims in the Medtronic patents but declined to invalidate the majority of asserted claims. The Company appealed the decisions on the claims that were not invalidated. Following these IPR decisions, the judge presiding over the litigation in the United States District Court for the Central District of California lifted the stay on litigation proceedings. The Company is currently engaged in discovery in the Medtronic Litigation.

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).

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 was expensed and recognized as interest expense.

In February 2021, the Company entered into another Loan and Security Agreement with Silicon Valley Bank, under which the Company obtained a loan in the principal amount of $75 million. The Loan under the Loan and Security Agreement matures on February 1, 2024, 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.

The loan allowed for prepayments of 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 the Company elects to prepay the Loan prior to the Maturity Date, the Company is 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 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 the Company is 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 the Company 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.

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.

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

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

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

Note 6. Stockholders' Equity

Preferred Stock

As of December 31, 2021, 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,		
	2021	**2020**	**2019**
Research and development	$ 5,980	$ 3,457	$ 1,725
General and administrative	8,079	5,852	3,950
Sales and marketing	11,105	5,786	3,045
	$ 25,164	$ 15,095	$ 8,720

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, 2021 and 2020, a total of 3,130,064 and 3,131,624 common shares have been reserved for issuance under the 2014 Plan, respectively. As of December 31, 2021 and 2020, there were no stock options 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 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 4,588,548. As of December 31, 2021 and 2020, there were 950,354 and 1,678,326 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,	
	2021	2020
Options outstanding under the 2014 Plan	277,505	501,598
Options and restricted stock-based awards outstanding under the 2018 Plan	2,502,885	2,477,929
Options and restricted stock-based awards remaining under the 2018 Plan for future issuance	950,354	1,678,326
	3,730,744	4,657,853

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

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

	Years Ended December 31,		
	2021	2020	2019
Expected term (in years)	5.46 - 6.00	6.05	5.07 - 6.16
Stock volatility	63.49%	72.01%	70.02% - 77.52%
Risk-free interest rate	0.53% - 1.16%	1.37%	1.42% - 2.56%
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 $32.93, $18.56, and $13.79 for the years ended December 31, 2021, 2020, and 2019 respectively.

As of December 31, 2021 and 2020, there was $6.7 million and $11.6 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 1.6 years and 2.4 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, 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	
Options granted	46,000	58.07	
Options exercised	(522,495)	12.60	$ 24,455 (1)
Options forfeited	(50,856)	29.64	
Outstanding at December 31, 2021	1,427,892	$ 18.13	$ 54,190 (2)
Options exercisable at December 31, 2021	917,909	$ 15.62	$ 37,064 (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 2021 and the stock option exercise price, multiplied by the number of in-the-money options as of December 31, 2021. 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 6.9 years and 7.7 years at December 31, 2021 and 2020, respectively.

Restricted Shares Awards Activity

As of December 31, 2021 and 2020, there was $42.5 million and $22.6 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 3.0 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, 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 shares awards granted	638,936	57.90
Restricted shares awards vested	(235,560)	31.19
Restricted shares awards forfeited	(118,525)	40.33
Outstanding at December 31, 2021	1,102,034	$ 46.07

Restricted Stock Units Activity

As of December 31, 2021 and 2020, there was $1.9 million and $1.2 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 0.9 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
Restricted stock units granted	212,417	43.62
Restricted stock units vested	(169,054)	19.89
Outstanding at December 31, 2021	250,464	$ 42.99

Stock Warrants

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, 2021 and 2020.

Note 7. Income Taxes

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

	Years Ended December 31,		
	2021	2020	2019
Domestic	$ (56,105)	$ (54,994)	$ (80,322)
Foreign	(23,180)	80	388
Total	$ (79,285)	$ (54,914)	$ (79,934)

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

	Years Ended December 31,		
	2021	2020	2019
Current:			
Federal	$ —	$ —	$ —
State	211	1	1
Foreign	26	—	—
Total current income tax expense	$ 237	$ 1	$ 1
Deferred:			
Federal	$ (422)	$ —	$ —
State	(117)	—	—
Foreign	1,084	—	—
Total deferred income tax expense	$ 545	$ —	$ —
Total	$ 782	$ 1	$ 1

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

	Years Ended December 31,		
	2021	2020	2019
Tax at statutory federal rate	21.0 %	21.0 %	21.0 %
State tax, net of federal benefit	3.8 %	7.0 %	7.0 %
Excess tax benefits related to stock-based compensation	9.4 %	10.3 %	(1.0)%
Non-deductible stock-based compensation	(1.4)%	— %	— %
Tax rate change	(5.2)%	— %	— %
Net operating loss adjustments	(7.9)%	— %	— %
Section 382 limitation	— %	— %	(5.0)%
R&D tax credit, net of reserve	6.1 %	(4.5)%	— %
Change in valuation allowance	(24.5)%	(36.8)%	(21.5)%
Other	(2.3)%	3.0 %	(0.5)%
Effective tax rate	(1.0)%	— %	— %

Our effective tax rate was 1.0% for the year ended December 31, 2021, compared to an effective tax rate of 0.0% for the year ended December 31, 2020 and 0.0% for the year ended December 31, 2019. The effective tax rates for the periods presented are primarily comprised of U.S. and foreign statutory taxes, excess tax benefits related to stock-based compensation, change in foreign statutory income tax rates, and a change in valuation allowance. The difference in the effective tax rate of 1.0% for the year ended December 31, 2021 as compared to the effective tax rate of 0.0% for the year ended December 31, 2020 was due to statutory tax rate increases in the U.K. offset by losses in certain foreign jurisdictions, of which are being benefited.

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

	December 31,	
	2021	**2020**
Deferred Tax Assets:		
Share-based compensation	$ 5,367	$ 592
Depreciation and amortization	7	145
Lease liability	895	901
Net operating loss carryforwards	74,744	59,176
Research and development credit carryforwards	4,865	—
Interest expense limitation carryforwards	2,518	—
Other	2,895	4,438
Total deferred tax assets	91,291	65,252
Less: valuation allowance	(85,061)	(65,252)
Total net deferred tax assets	$ 6,230	$ —
Deferred Tax Liabilities:		
Intangibles	$ (25,447)	$ —
Total deferred tax liabilities	$ (25,447)	$ —
Net deferred tax liabilities	$ (19,217)	$ —

At December 31, 2021, the Company had U.S. federal and foreign net operating loss (NOL) carryforwards of approximately $258.2 million and $16.4 million, respectively. Of the U.S. federal NOLs, $51.5 million will expire between 2033 and 2037 and the remainder will carryover indefinitely. The Company had U.S. state NOLs of $245.6 million, which will expire between 2033 and 2041. 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 foreign net operating loss carryforwards have an indefinite carryforward period.

The Company accounts for income taxes according to ASC 740. The Company periodically evaluates whether a portion or all of its deferred tax assets will be recovered. The Company records a valuation allowance against deferred tax assets if and to the extent it is more likely than not that they will not be recovered. In evaluating the need for a valuation allowance, the Company weighs all relevant positive and negative evidence, including among other factors, historical financial performance, forecasts of income over the applicable carryforward periods, and the market environment, with each consideration weighted based on its reliability. The Company continues to maintain a full valuation allowance against its otherwise recognizable U.S. deferred income tax assets as of December 31, 2021 and 2020. 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 $19.8 million for the year ended December 31, 2021, from $65.3 million to $85.1 million. This increase in the valuation allowance during the year ended December 31, 2021, was largely

attributable to losses incurred in the U.S. jurisdiction. The Company's NOL carryforwards were generated from domestic and foreign operations.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code), use of the Company's NOL carryforwards may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a rolling three-year period. The Company performed an analysis of changes in ownership for purposes of these Internal Revenue Code sections. Based on the 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. Based on the study performed in 2021, the Company determined that an ownership change did not occur in 2021. 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 applies the provisions of FASB 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 has identified unrecognized tax benefits or uncertain tax positions. There has been a liability on uncertain tax positions recorded on the financial statements as of December 31, 2021. The Company does not expect that its assessment regarding unrecognized tax benefits and uncertain tax positions will materially change over the following 12 months.

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

Balance at December 31, 2019	$ —
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
Additions based on tax positions related to the current year	528
Additions from business combination	1,782
Deductions for tax positions taken in prior years	(1,397)
Balance at December 31, 2021	$ 3,404

As of December 31, 2021, the total unrecognized tax benefits was $3.4 million, of which, if recognized, $0.1 million would affect the annual effective tax rate. Additionally, approximately $1.7 million of the unrecognized tax position is subject to an indemnification, and as such these amounts will not result in economic exposure for the Company. The Company does not believe that the amount of unrecognized tax benefits will change significantly in the next 12 months. As of December 31, 2021, the Company has accumulated $0.4 million in both interest and penalties associated with uncertain tax positions. There were no interest or penalties to be recognized for the tax years ended December 31, 2020, and 2019.

The Company has net operating loss and research and development credit carryforwards which may be subject to examination by taxing authorities. As of December 31, 2021, tax years beginning with the year ended December 31, 2017 remain subject to examination by the Internal Revenue Service and certain U.S. state jurisdictions. As of December 31, 2021, tax years beginning with the years ended December 31, 2015, December 31, 2017, and December 31, 2017 remain subject to examination by the German, French, and the U.K. tax authorities, respectively. The Company is not currently under audit by any taxing authority.

Note 8. Employee Benefit Plan

The Company sponsors a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all 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, 2021, 2020, and 2019, the Company contributions to the plan amounted to $1.9 million, $1.6 million, and $1.1 million, respectively.

Note 9. Acquisition

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

The Company accounted for the acquisition as a business combination pursuant to ASC 805. In accordance with ASC 805, fair values are assigned to tangible and identifiable intangible assets acquired and liabilities assumed at the acquisition date based on the information that was available as of the acquisition date. The Company believes that the information available provides a reasonable basis for estimating the fair values of assets acquired and liabilities assumed for the acquisition.

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

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

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

Intangible assets

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

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

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

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

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

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

Intangible assets will be amortized based on their useful life. $6.5 million in amortization expense relating to these intangible assets was recognized during the year ended December 31, 2021 in the consolidated statements of comprehensive loss. The unamortized balance as of December 31, 2021 was $103.7 million. The total weighted-average original amortization period for the acquired finite-lived intangible assets is 12 years.

Goodwill

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

Contingent consideration

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

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

Deferred tax liabilities

After the March 31, 2021 interim financial statements were issued, the Company received a preliminary tax provision report from a third-party tax firm. After considering the results of that tax provision report, the Company preliminarily estimated the fair value of the deferred tax liabilities assumed to be $17.9 million. As a result, the fair value of the deferred tax liabilities increased by $17.9 million with a corresponding increase to goodwill.

After the June 30, 2021 interim financial statements were issued, the Company received an updated preliminary tax provision report from a third-party tax firm. After considering the results of that tax provision report, the Company estimated the fair value of the deferred tax liabilities assumed to be $23.8 million. As a result, the fair value of the deferred tax liabilities increased by $5.9 million with a corresponding increase to goodwill.

After the September 30, 2021 interim financial statements were issued, the Company received a final tax provision report from a third-party tax firm. After considering the results of that tax provision report, the Company estimated the fair value of the deferred tax liabilities assumed to be $19.3 million. As a result, the fair value of the deferred tax liabilities decreased by $4.5 million with a corresponding decrease to goodwill.

Transaction-related costs

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

Pro forma (Unaudited)

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

	Years Ended December 31,	
	2021	**2020**
Net revenue	$ 181,643	$ 122,444
Net loss	$ (77,535)	$ (63,183)
Net loss per share, basic and diluted	$ (1.79)	$ (1.66)
Weighted-average shares used to compute basic and diluted net loss per share	43,237,536	38,077,918

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

- An adjustment to decrease net loss for the year ended December 31, 2021 by $4.4 million to eliminate integration and acquisition related costs incurred by the Company and Contura and a corresponding increase to net loss for the year ended December 31, 2020 by $4.4 million to give effect to the integration and acquisition of Contura as if it had occurred on January 1, 2020.
- An adjustment to increase net loss for the year ended December 31, 2021 by $1.3 million and a corresponding increase to net loss for the year ended December 31, 2020 by $7.8 million to reflect amortization of the fair value adjustments for intangible assets as if the assets were acquired January 1, 2020.
- An adjustment to decrease net loss for the year ended December 31, 2020 by $2.2 million to reflect remeasurement of the fair value adjustments for deferred tax liabilities as if the liabilities were assumed January 1, 2020.

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, 2021, the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2021 due to the material weakness in internal control over financial reporting, as described below.

Management's Annual Report on Internal Control Over Financial Reporting

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

Management has conducted, with the participation of our Principal Executive Officer and our Chief Financial Officer, an assessment, including testing of the effectiveness, of our internal control over financial reporting as of December 31, 2021. Management's assessment of internal control over financial reporting was conducted using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework (2013 Framework). Based on its assessment, management has concluded that our internal control over financial reporting was not effective as of December 31, 2021 due to a material weakness in our internal control over financial reporting described below.

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

Management's assessment of the Company's internal control over financial reporting as of December 31, 2021 determined that a material weakness exists relating to the determination of the fair values of identifiable intangible assets and contingent consideration liability related to business combination. This control deficiency creates a reasonable possibility that a material misstatement to the consolidated financial statements will not be prevented or detected on a timely basis, and therefore, we concluded that the deficiency represents a material weakness in our internal control over financial reporting, and our internal control over financial reporting was not effective as of December 31, 2021.

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

BDO USA, LLP, an independent registered public accounting firm, who audited the consolidated financial statements included in this annual report, has expressed an adverse opinion on the operating effectiveness of the Company's internal control over financial reporting as of December 31, 2021. BDO USA, LLP's report appears below.

Remediation Plan

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

- Enhancing the design of controls, including the precision of the management review controls relating to key methodologies, assumptions and inputs used in the determination of the fair value of identifiable intangibles and a contingent consideration liability;
- Implementing a valuation review checklist that includes specific review attributes to ensure sufficient evidence of an effective review is documented and maintained to support management's conclusions; and
- Expanding personnel with appropriate experience to devote sufficient time and resources to our internal controls over fair value measurements.

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

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

Changes in internal control over financial reporting

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

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Axonics, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness regarding management's failure to design and implement controls over the determination of the fair values of identifiable intangible assets and contingent consideration liability in a business combination has been identified and described in management's assessment. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2021 consolidated financial statements, and this report does not affect our report dated March 1, 2022 on those consolidated financial statements.

Definition and Limitations of Internal Control over Financial Reporting

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

assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ BDO USA, LLP
Costa Mesa, California
March 1, 2022

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to our definitive proxy statement to be filed within 120 days of December 31, 2021 and delivered to stockholders in connection with our 2022 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, 2021 and delivered to stockholders in connection with our 2022 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, 2021 and delivered to stockholders in connection with our 2022 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, 2021 and delivered to stockholders in connection with our 2022 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, 2021 and delivered to stockholders in connection with our 2022 annual meeting of stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

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

1. Consolidated Financial Statements:

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

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

Consolidated Balance Sheets

Consolidated Statements of Comprehensive Loss

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

2. Financial Statement Schedules:

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

3. Exhibits:

EXHIBIT INDEX

Exhibit Number	Exhibit Title	Incorporated by Reference				Filed Herewith (X)
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-38721	3.1	11/5/2018	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Registrant filed April 1, 2021.	8-K	001-38721	3.1	4/1/2021	
3.3	Amended and Restated Bylaws.	8-K	001-38721	3.2	11/5/2018	
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.	10-K	001-38721	4.4	3/1/2021	
10.1+	2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.8	10/22/2018	
10.2+	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	Loan and Security Agreement, dated as of February 25, 2021, by and among Silicon Valley Bank and Axonics, Inc.	10-Q	001-38721	10.3	5/7/2021
10.11	Lease, dated November 30, 2017, by and between The Irvine Company LLC and the Registrant.	S-1	333-227732	10.13	10/5/2018
10.12	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
10.13	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
10.14	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
10.15+	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
10.16+	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
10.17+	Executive Employment Agreement, dated June 5, 2019, by and between Rinda Sama and the Registrant.	10-Q	001-38721	10.4	8/5/2019
10.18	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
10.19	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
10.20	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

10.21	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	
10.22	Form of Indemnification Agreement by and between the Registrant and its directors and officers.	S-1/A	333-227732	10.12	10/22/2018	
10.23	Agreement, dated February 25, 2021, by and among Axonics, Inc., Axonics Modulation Technologies, U.K. Limited and Contura Holdings.	10-Q	001-38721	10.1	5/7/2021	
10.24	Exclusive Manufacturing and Supply Agreement, dated February 25, 2021, by and between Contura International A/S and Contura Limited.	10-Q	001-38721	10.2	5/7/2021	
21.1	List of Subsidiaries.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
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, INC.

Date: March 1, 2022

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, 2022	By:	/s/ Raymond W. Cohen Raymond W. Cohen Chief Executive Officer and Director (Principal Executive Officer)
Date: March 1, 2022	By:	/s/ Dan L. Dearen Dan L. Dearen President and Chief Financial Officer (Principal Financial and Accounting Officer)
Date: March 1, 2022	By:	/s/ Michael H. Carrel Michael H. Carrel Chairman of the Board and Director
Date: March 1, 2022	By:	/s/ Jane E. Kiernan Jane E. Kiernan Director
Date: March 1, 2022	By:	/s/ Robert E. McNamara Robert E. McNamara Director
Date: March 1, 2022	By:	/s/ Nancy Snyderman, M.D., FACS Nancy Snyderman, M.D., FACS Director
Date: March 1, 2022	By:	/s/ David M. Demski David M. Demski Director
Date: March 1, 2022	By:	/s/ Esteban López Esteban López, M.D. Director

Exhibit 21.1

List of Subsidiaries of
Axonics, Inc.

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Axonics, 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, Inc. ("Company") of our reports dated March 1, 2022, relating to the consolidated financial statements and the effectiveness of Axonics, Inc.'s internal control over financial reporting, which appear in this Form 10-K. Our report on the effectiveness of internal control over financial reporting expresses an adverse opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2021.

/s/ BDO USA, LLP
Costa Mesa, California

March 1, 2022

Exhibit 31.1

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

I, Raymond W. Cohen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 1, 2022

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, 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, 2022

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, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021 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, 2022

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

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

Exhibit 32.2

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

In connection with the Annual Report of Axonics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021 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, 2022

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, Inc. and will be retained by Axonics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.