

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

---

**FORM 10-Q**

---

- (Mark One)
- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2020  
or  
 **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_
- Commission File Number: 001-38721

---

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

---

<p style="text-align: center;"><b>Delaware</b> (State or other jurisdiction of incorporation or organization)</p> <p style="text-align: center;"><b>26 Technology Drive</b> <b>Irvine, California</b> (Address of principal executive offices)</p>	<p style="text-align: center;"><b>45-4744083</b> (I.R.S. Employer Identification Number)</p> <p style="text-align: center;"><b>92618</b> (Zip Code)</p> <p style="text-align: center;"><b>(949) 396-6322</b> (Registrant's telephone number, including area code)</p>
--	---

Securities registered pursuant to Section 12(b) of the Exchange Act:

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

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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
	Emerging growth company <input checked="" type="checkbox"/>

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

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

As of November 2, 2020, 39,809,412 shares of the registrant's common stock, par value \$0.0001 per share, were outstanding.

---

---

## TABLE OF CONTENTS

Page

---

[Special Note Regarding Forward-Looking Statements](#)

### **PART I—FINANCIAL INFORMATION**

<a href="#">Item 1.</a>	<a href="#">Condensed Consolidated Financial Statements (unaudited)</a>	<a href="#">1</a>
	<a href="#">Condensed Consolidated Balance Sheets</a>	<a href="#">1</a>
	<a href="#">Condensed Consolidated Statements of Comprehensive Loss</a>	<a href="#">2</a>
	<a href="#">Condensed Consolidated Statements of Stockholders' Equity</a>	<a href="#">3</a>
	<a href="#">Condensed Consolidated Statements of Cash Flows</a>	<a href="#">5</a>
	<a href="#">Notes to Condensed Consolidated Financial Statements</a>	<a href="#">6</a>
<a href="#">Item 2.</a>	<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	<a href="#">21</a>
<a href="#">Item 3.</a>	<a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	<a href="#">31</a>
<a href="#">Item 4.</a>	<a href="#">Controls and Procedures</a>	<a href="#">31</a>

### **PART II—OTHER INFORMATION**

<a href="#">Item 1.</a>	<a href="#">Legal Proceedings</a>	<a href="#">32</a>
<a href="#">Item 1A.</a>	<a href="#">Risk Factors</a>	<a href="#">32</a>
<a href="#">Item 2.</a>	<a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	<a href="#">34</a>
<a href="#">Item 3.</a>	<a href="#">Defaults Upon Senior Securities</a>	<a href="#">34</a>
<a href="#">Item 4.</a>	<a href="#">Mine Safety Disclosures</a>	<a href="#">34</a>
<a href="#">Item 5.</a>	<a href="#">Other Information</a>	<a href="#">34</a>
<a href="#">Item 6.</a>	<a href="#">Exhibits</a>	<a href="#">35</a>
	<a href="#">Signatures</a>	<a href="#">36</a>

---

## Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 proprietary rechargeable sacral neuromodulation (SNM) system (r-SNM System);
  - U.S. Food and Drug Administration (FDA) or other U.S. or foreign regulatory or legal actions or changes affecting us or our industry;
  - 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;
  - announcements of regulatory approval or disapproval of our r-SNM and any future enhancements to our r-SNM System;
  - adverse results from or delays in clinical studies of our r-SNM System;
  - variations in our financial results or those of companies that are perceived to be similar to us;
  - success or failure of competitive products or therapies in the SNM market;
  - changes in the structure of healthcare payment of our r-SNM System;
  - announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
  - market conditions in the medical technology industry and issuance of securities analysts’ reports or recommendations;
  - rumors and market speculation involving us or other companies in our industry;
  - sales of substantial amounts of our stock by directors, officers or significant stockholders, or the expectation that such sales might occur;
  - general economic, industry and market conditions, including the size and growth, if any, of the market;
  - additions or departures of key personnel;
  - changes in our capital structure, such as future issuances of securities and the incurrence of additional debt;
  - the results of any ongoing or future legal proceedings; and
  - the continued impact of the novel coronavirus (COVID-19) pandemic, and the related responses of the government and consumers on our business, financial condition and results of operations.
-

The forward-looking statements included herein are based on current expectations of our management based on available information and involve a number of risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond our control. As such, our actual results may differ significantly from those expressed in any forward-looking statements. Factors that may cause or contribute to such differences include, but are not limited to, those discussed in more detail in Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of Part I and Item 1A “Risk Factors” of Part II of this Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, the terms “Axonics,” “our company,” “we,” “us” and “our” refer to Axonics Modulation Technologies, Inc. and our consolidated subsidiaries.

This Quarterly Report on Form 10-Q includes our trademarks and trade names, including, without limitation, r-SNM® and Axonics SNM System®, which are our property and are protected under applicable intellectual property laws. Solely for convenience, trademarks and trade names referred to in this Quarterly Report on Form 10-Q 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—Financial Information****Item 1. Condensed Consolidated Financial Statements (unaudited)**

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

	September 30, 2020	December 31, 2019
	(unaudited)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 269,280	\$ 171,082
Short-term investments	—	12,592
Accounts receivable, net of allowance for doubtful accounts of \$465 and \$75 at September 30, 2020 and December 31, 2019, respectively	17,650	7,879
Inventory, net	44,308	15,659
Prepaid expenses and other current assets	3,220	4,468
Total current assets	334,458	211,680
Property and equipment, net	5,792	3,047
Intangible asset, net	225	311
Other assets	7,196	4,784
Total assets	\$ 347,671	\$ 219,822
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 9,415	\$ 5,882
Accrued liabilities	5,977	2,174
Accrued compensation and benefits	7,516	3,375
Operating lease liability, current portion	908	602
Debt, current portion	15,000	—
Total current liabilities	38,816	12,033
Operating lease liability, net of current portion	9,027	4,450
Debt, net of unamortized debt issuance costs, net of current portion	5,930	20,336
Total liabilities	53,773	36,819
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at September 30, 2020 and December 31, 2019; 39,753,638 and 34,110,995 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	4	3
Additional paid-in capital	517,659	363,012
Accumulated deficit	(223,151)	(179,584)
Accumulated other comprehensive loss	(614)	(428)
Total stockholders' equity	293,898	183,003
Total liabilities and stockholders' equity	\$ 347,671	\$ 219,822

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net revenue	\$ 35,243	\$ 1,309	\$ 76,752	\$ 3,874
Cost of goods sold	13,434	632	31,792	1,952
Gross profit	21,809	677	44,960	1,922
Operating Expenses				
Research and development	7,748	4,855	21,030	13,948
General and administrative	5,773	5,162	18,963	13,539
Sales and marketing	17,057	15,707	47,846	32,371
Total operating expenses	30,578	25,724	87,839	59,858
Loss from operations	(8,769)	(25,047)	(42,879)	(57,936)
Other Income (Expense)				
Interest income	35	627	742	2,500
Interest and other expense	(434)	(586)	(1,429)	(1,747)
Other income (expense), net	(399)	41	(687)	753
Loss before income tax expense	(9,168)	(25,006)	(43,566)	(57,183)
Income tax expense	—	—	1	1
Net loss	(9,168)	(25,006)	(43,567)	(57,184)
Foreign currency translation adjustment	99	(112)	(186)	(165)
Comprehensive loss	\$ (9,069)	\$ (25,118)	\$ (43,753)	\$ (57,349)
Net loss per share, basic and diluted (see Note 1)	\$ (0.24)	\$ (0.89)	\$ (1.20)	\$ (2.05)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	38,830,924	28,098,564	36,312,984	27,958,376

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
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	181,456	—	344	—	—	344
Restricted Shares Award (RSA) issuances and forfeitures for terminations, net and stock-based compensation	171,875	—	3,039	—	—	3,039
Restricted Stock Units (RSU) issuances and forfeitures for terminations, net and stock-based compensation	46,336	—	883	—	—	883
Foreign currency translation adjustment	—	—	—	—	(177)	(177)
Net loss	—	—	—	(14,616)	—	(14,616)
Balance at March 31, 2020	34,510,662	3	367,278	(194,200)	(605)	172,476
Issuance of common stock for employee stock option exercises for cash	319,680	—	1,008	—	—	1,008
RSA issuances and forfeitures for terminations, net and stock-based compensation	32,063	—	2,969	—	—	2,969
RSU issuances and forfeitures for terminations, net and stock-based compensation	—	—	847	—	—	847
Follow-on offering - issuance of 4,600,000 shares at \$32.50 per share, less closing costs of \$9,013	4,600,000	1	140,486	—	—	140,487
Foreign currency translation adjustment	—	—	—	—	(108)	(108)
Net loss	—	—	—	(19,783)	—	(19,783)
Balance at June 30, 2020	39,462,405	4	512,588	(213,983)	(713)	297,896
Issuance of common stock for employee stock option exercises for cash	164,233	—	1,296	—	—	1,296
RSA issuances and forfeitures for terminations, net and stock-based compensation	127,000	—	2,920	—	—	2,920
RSU issuances and forfeitures for terminations, net and stock-based compensation	—	—	855	—	—	855
Foreign currency translation adjustment	—	—	—	—	99	99
Net loss	—	—	—	(9,168)	—	(9,168)
Balance at September 30, 2020	39,753,638	\$ 4	\$ 517,659	\$ (223,151)	\$ (614)	\$ 293,898

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
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	41,740	—	44	—	—	44
RSA issuances and forfeitures for terminations, net and stock-based compensation	352,417	—	977	—	—	977
RSU issuances and forfeitures for terminations, net and stock-based compensation	—	—	165	—	—	165
Foreign currency translation adjustment	—	—	—	—	(10)	(10)
Net loss	—	—	—	(13,117)	—	(13,117)
Balance at March 31, 2019	28,201,091	3	244,523	(112,766)	(426)	131,334
Issuance of common stock for employee stock option exercises for cash	136,164	—	308	—	—	308
RSA issuances and forfeitures for terminations, net and stock-based compensation	112,417	—	1,629	—	—	1,629
RSU issuances and forfeitures for terminations, net and stock-based compensation	—	—	246	—	—	246
Issuance of common stock for warrant exercise	31,071	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	(43)	(43)
Net loss	—	—	—	(19,061)	—	(19,061)
Balance at June 30, 2019	28,480,743	3	246,706	(131,827)	(469)	114,413
Issuance of common stock for employee stock option exercises for cash	82,756	—	111	—	—	111
RSA issuances and forfeitures for terminations, net and stock-based compensation	37,883	—	2,534	—	—	2,534
RSU issuances and forfeitures for terminations, net and stock-based compensation	—	—	248	—	—	248
Issuance of common stock for warrant exercise	32,529	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	(112)	(112)
Net loss	—	—	—	(25,006)	—	(25,006)
Balance at September 30, 2019	28,633,911	\$ 3	\$ 249,599	\$ (156,833)	\$ (581)	\$ 92,188

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (43,567)	\$ (57,184)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,253	880
Stock-based compensation	11,513	5,799
Amortization of debt issuance costs	594	659
Provision for doubtful accounts	390	—
Other items, net	142	—
Changes in operating assets and liabilities		
Accounts receivable	(10,161)	(527)
Inventory	(28,600)	(9,030)
Prepaid expenses and other current assets	1,352	1,091
Other assets	16	(327)
Accounts payable	3,533	796
Accrued liabilities	3,508	532
Accrued compensation and benefits	4,141	2,089
Lease liability	458	(96)
Net cash used in operating activities	(55,428)	(55,318)
<b>Cash Flows from Investing Activities</b>		
Purchases of property and equipment	(1,915)	(962)
Purchases of short-term investments	—	(35,210)
Proceeds from sales and maturities of short-term investments	12,592	69,117
Net cash provided by investing activities	10,677	32,945
<b>Cash Flows from Financing Activities</b>		
Proceeds from issuance of common stock upon follow-on public offering	149,500	—
Payment of common stock issuance costs upon follow-on public offering	(9,013)	—
Proceeds from exercise of stock options	2,648	463
Net cash provided by financing activities	143,135	463
Effect of exchange rate changes on cash and cash equivalents	(186)	(165)
Net increase (decrease) in cash and cash equivalents	98,198	(22,075)
Cash and cash equivalents, beginning of year	171,082	98,306
Cash and cash equivalents, end of period	\$ 269,280	\$ 76,231
<b>Supplemental Disclosure of Cash Flow Information</b>		
Cash paid for interest	\$ 849	\$ 1,097
Cash paid for taxes	\$ —	\$ 1

See accompanying notes to unaudited condensed consolidated financial statements.

**AXONICS MODULATION TECHNOLOGIES, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

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

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

***Initial Public Offering***

On November 2, 2018, the Company completed its initial public offering (IPO) by issuing 9,200,000 shares of common stock, at an offering price of \$15.00 per share, inclusive of 1,200,000 shares of the Company's common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The net proceeds were approximately \$126.0 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company. In connection with the IPO, the Company's outstanding shares of convertible preferred stock were automatically converted into an aggregate of 15,813,297 shares of common stock, and the Company's outstanding warrants to purchase shares of Series C convertible preferred stock were automatically converted into warrants to purchase up to an aggregate of 80,000 shares of common stock (see Note 5).

***November 2019 Follow-On Offering***

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

***May 2020 Follow-On Offering***

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

***Principles of Consolidation***

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

## **Basis of Presentation**

### *Interim Financial Statements*

The interim condensed consolidated financial statements and related footnote disclosures as of and for the three and nine months ended September 30, 2020 are unaudited, and are not necessarily indicative of the Company's operating results for a full year. The unaudited interim condensed consolidated financial statements include all normal and recurring adjustments necessary for a fair presentation of the Company's financial results for the three and nine months ended September 30, 2020 in accordance with United States (U.S.) generally accepted accounting principles (GAAP), however, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the U.S. Securities and Exchange Commission (SEC) rules and regulations relating to interim financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included within the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (filed with the SEC on March 4, 2020).

### **COVID-19**

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

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

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

### **Use of Estimates**

The preparation of condensed consolidated financial statements in conformity with GAAP requires the Company's management to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses, and related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and such differences may be material to the consolidated financial statements.

**Revenue Recognition**

Revenue recognized during the three and nine months ended September 30, 2020 and 2019 relates entirely to the sale of our r-SNM System. In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09 “Revenue from Contracts with Customers” (ASU 2014-09) as Accounting Standards Codification (ASC) Topic 606. The objective of Topic 606 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and superseded most of the existing revenue recognition guidance, including industry-specific guidance. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Topic 606 applies to all contracts with customers except those that are within the scope of other topics in the FASB ASC.

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

In accordance with Company policy and based on the Company’s historical experience, the allowance for product returns was \$0.3 million and zero at September 30, 2020 and December 31, 2019, respectively. Damaged or defective products are replaced at no charge under the Company’s standard warranty. For the nine months ended September 30, 2020, the replacement costs were \$0.1 million. For the three months ended September 30, 2020 and three and nine months ended September 30, 2019, the replacement costs were minimal.

The following table provides additional information pertaining to net revenue disaggregated by geographic market for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
United States	\$ 34,139	\$ —	\$ 73,833	\$ —
International markets	1,104	1,309	2,919	3,874
<b>Total net revenue</b>	<b>\$ 35,243</b>	<b>\$ 1,309</b>	<b>\$ 76,752</b>	<b>\$ 3,874</b>

**Allowance for Doubtful Accounts**

The Company makes estimates of the collectability of accounts receivable. In doing so, the Company analyzes historical bad debt trends, customer credit worthiness, current economic trends and changes in customer payment patterns when evaluating the adequacy of the allowance for doubtful accounts. Despite the Company’s efforts to minimize credit risk exposure, clients could be adversely affected if future economic and industry trends, including those related to COVID-19, change in such a manner as to negatively impact their cash flows. The full effects of COVID-19 on the Company’s clients are highly uncertain and cannot be predicted. As a result, the Company’s future collection experience can differ significantly from historical collection trends. If the Company’s clients experience a negative impact on their cash flows, it could have a material adverse effect on the Company’s results of operations and financial condition.

### ***Cash and Cash Equivalents***

Cash equivalents consist of short-term, highly liquid investments purchased with an original maturity of three months or less. Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. At times, the cash and cash equivalent balances may exceed federally insured limits. The Company does not believe that this results in any significant credit risk.

### ***Fair Value of Financial Instruments***

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

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

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

### ***Investment Securities***

The Company classifies its investment securities as available-for-sale. Those investments in debt securities with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments in debt securities with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based on the fair value hierarchy (Level 1 and Level 2 inputs in the fair value hierarchy), and consists primarily of commercial paper, corporate notes and U.S. government and agency securities. Unrealized gains or losses, deemed temporary in nature, are reported as other comprehensive income within the condensed consolidated statement of comprehensive income (loss). There were no unrealized gains or losses during the three and nine months ended September 30, 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 (accrued) over the life of the related security as an adjustment to yield using the straight-line interest method. Dividend and interest income are recognized when earned. Realized gains or losses are included in net income (loss) and are derived using the specific identification method for determining the cost of securities sold.

The following table presents the fair value hierarchy for those assets measured at fair value on a recurring basis as of September 30, 2020 and December 31, 2019 (in thousands):

<b>Fair Value Measurements at September 30, 2020</b>				
<b>Assets:</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Commercial paper	\$ —	\$ —	\$ —	\$ —
Corporate notes	—	—	—	—
U.S. government and agency securities	—	—	—	—
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

  

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

### **Foreign Currency Translation**

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Costs and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' equity in accumulated other comprehensive loss until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss). As of September 30, 2020 and December 31, 2019, all foreign currency translation gains (losses) have been unrealized and included in accumulated other comprehensive loss. Accumulated other comprehensive loss consists entirely of losses or gains from translation of foreign subsidiaries at September 30, 2020 and December 31, 2019. Foreign currency transaction gains and losses are included in results of operations and have not been significant for the periods presented.

### **Inventory, Net**

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

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

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

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

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

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

As of September 30, 2020, the Company had \$23.0 million, \$6.1 million and \$15.2 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, on hand net of reserves that were minimal. As of December 31, 2019, the Company had \$7.0 million, \$1.5 million and \$7.2 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, on hand net of reserves of \$0.1 million.

#### ***Vendor Concentration***

As of September 30, 2020 and December 31, 2019, there was one and no vendor, respectively, who accounted for over 10% of the Company's consolidated accounts payable.

#### ***Property and Equipment***

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

#### ***Intangible Asset***

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The additional field-of-use was provided in exchange for 50,000 shares of Series A preferred stock, the fair value of which was \$1.0 million in 2013. The intangible asset was recorded at its fair value of \$1.0 million at the date contributed. In connection with the IPO, such shares of Series A preferred stock were converted into common stock. Amortization of this asset is recorded over the shorter of the patent or legal life on a straight-line basis. The weighted-average amortization period is 8.71 years. Accumulated amortization of the intangible asset is \$0.8 million and \$0.7 million at September 30, 2020 and December 31, 2019, respectively. The Company recorded expense for the amortization of intangible assets of \$0.1 million during the nine months ended September 30, 2020 and 2019. The amortization of the intangible asset was minimal during the three months ended September 30, 2020 and 2019. The Company will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date.

#### ***Impairment of Long-Lived Assets***

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net cash flows that the assets are expected to generate. If said assets are considered to be impaired, the impairment that would be recognized is measured by the amount by which the carrying amount of

the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets to date.

### **Leases**

Effective January 1, 2018, the Company early adopted ASU No. 2016-02, "Leases (Topic 842)", the comprehensive new lease standard issued by the FASB. The most significant impact was the recognition of right-of-use (ROU) assets and lease liabilities for operating leases. The Company determines if an arrangement is a lease at inception and includes operating leases on the Company's consolidated balance sheets. The operating lease ROU asset is included within the Company's other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company's condensed consolidated balance sheets.

The Company has made certain policy elections to apply to its leases executed post-adoption, or subsequent to January 1, 2018. In accordance with Topic 842, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components. Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only. Topic 842 allows for the use of judgment in determining whether the assumed lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. The Company applies the bright line thresholds referenced in Topic 842 to assist in evaluating leases for appropriate classification. The aforementioned bright lines are applied consistently to the Company's entire portfolio of leases.

Operating lease ROU asset and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. As of September 30, 2020 and December 31, 2019, the weighted-average remaining lease terms for the Company's operating leases were 7.2 years and 7.8 years, respectively. The weighted-average discount rate used to determine the present value of the Company's operating leases' future payments was 6.9% and 7.25% as of September 30, 2020 and December 31, 2019, respectively (see Note 3 regarding leases).

### **Research and Development**

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

### **Income Taxes**

The Company accounts for income taxes using the asset and liability method to compute the difference between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. The Company has deferred tax assets. The realization of these deferred tax assets is dependent upon the Company's ability to generate sufficient taxable income in future years. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. The Company evaluates the recoverability of the deferred tax assets annually, and maintains a full valuation allowance on its deferred tax assets. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The Company has determined that it has no uncertain tax positions.

### ***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. Performance awards are expensed over the performance period based on the probability of achieving the performance objectives. In addition, the Company also grants market-based restricted stock units that have combined market conditions and service conditions for vesting, for which the Company uses the Monte Carlo valuation model to value equity awards (as of the date of grant).

### ***Net Loss per Share of Common Stock***

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

For the three and nine months ended September 30, 2020, there were 2,279,353 and 2,251,155 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. For the three and nine months ended September 30, 2019, there were 2,286,802 and 1,812,578 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.

### ***Recent Accounting Pronouncements***

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

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

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments," which updates the methodology used to measure current

expected credit losses (CECL). This guidance applies to financial assets measured at amortized cost, including loans, held-to-maturity debt securities, net investments in leases, and trade accounts receivable as well as certain off-balance sheet credit exposures, such as loan commitments. This guidance replaces the current incurred loss impairment methodology with a methodology to reflect CECL and requires consideration of a broader range of reasonable and supportable information to explain credit loss estimates. The guidance must be adopted using a modified retrospective transition method through a cumulative-effect adjustment to retained earnings (deficit) in the period of adoption. This guidance is expected to be effective for the Company at December 31, 2020, with early adoption permitted. The Company is currently evaluating the impact this guidance will have on the Company's consolidated financial statements or related disclosures as well as the timing of adoption.

## Note 2. Property and Equipment

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

	September 30, 2020	December 31, 2019
Research and development equipment	\$ 1,422	\$ 1,086
Computer hardware and software	1,744	1,418
Tools and molds	1,668	1,303
Leasehold improvements	3,749	1,500
Furniture and fixtures	1,331	624
Construction in progress	105	176
	<u>10,019</u>	<u>6,107</u>
Less: accumulated depreciation and amortization	(4,227)	(3,060)
	<u>\$ 5,792</u>	<u>\$ 3,047</u>

Depreciation and amortization expense of property and equipment was \$0.5 million and \$1.2 million for the three and nine months ended September 30, 2020, respectively. Depreciation and amortization expense of property and equipment was \$0.3 million and \$0.8 million for the three and nine months ended September 30, 2019, respectively.

## Note 3. 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. Upon the execution of the amendment, which was deemed to be a lease modification, the Company reassessed the lease liability using the discount rate at the modification date and recorded ROU assets for the same amount. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term.

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

of the commencement of the applicable renewal term. In the event of a default of certain of the Company's obligations under the lease, the Company's landlord would have the right to terminate the lease.

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

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

The Company did not control the leased premises under the New Lease before the commencement date. The aggregate base rent due over the Initial Term under the terms of the New Lease is approximately \$0.3 million (without giving effect to certain rent abatement terms). The Company is also responsible for the payment of additional rent to cover certain costs, taxes, and insurance (Additional Rent). The estimated Additional Rent during the Initial Term of the New Lease is approximately \$0.1 million. The Company also paid minimal amounts for leasehold improvements, net of the minimal tenant improvement allowance provided in the New Lease.

During the three and nine months ended September 30, 2020, ROU assets obtained in exchange for new operating lease liabilities were none and \$3.0 million, respectively. During the three and nine months ended September 30, 2019, ROU assets obtained in exchange for new operating lease liabilities were none and \$1.5 million, respectively. As of September 30, 2020 and December 31, 2019, the ROU asset has a balance of \$6.6 million and \$4.2 million, respectively. The operating lease ROU asset is included within the Company's other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company's condensed consolidated balance sheets. During the three and nine months ended September 30, 2020, cash paid for amounts included in operating lease liabilities were \$0.4 million and \$1.0 million, respectively. During the three and nine months ended September 30, 2019, cash paid for amounts included in operating lease liabilities were \$0.3 million and \$0.7 million, respectively. Amortization of the ROU asset was \$0.2 million and \$0.6 million for the three and nine months ended September 30, 2020, respectively. Amortization of the ROU asset was \$0.2 million and \$0.3 million for the three and nine months ended September 30, 2019, respectively.

As of September 30, 2020 and December 31, 2019, the weighted-average remaining lease term for the Company's operating leases were 7.2 years and 7.8 years, respectively. The weighted-average discount rate used to determine the present value of the Company's operating leases' future payments was 6.9% and 7.25% as of September 30, 2020 and December 31, 2019, respectively.

Total lease cost for the three and nine months ended September 30, 2020 and 2019 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Lease cost				
Operating lease cost	\$ 491	\$ 281	\$ 1,472	\$ 761
Short-term lease cost	51	43	119	150
Variable lease cost	65	55	123	98
Total lease cost	\$ 607	\$ 379	\$ 1,714	\$ 1,009

### **License Agreement**

In October 2013, the Company entered into the License Agreement, pursuant to which AMF licensed the Company certain patents and know-how (collectively, the AMF IP) relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (collectively, the AMF Licensed Products). Under the License Agreement, for each calendar year beginning in 2018, the Company is obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to the Company by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) the Minimum Royalty, payable quarterly. The Minimum Royalty will automatically increase each year after 2018, subject to a maximum amount of \$200,000 per year. The Company generated net revenue of \$35.2 million and \$76.8 million during the three and nine months ended September 30, 2020, respectively, and recorded related royalties of \$1.4 million and \$3.0 million during the three and nine months ended September 30, 2020, respectively. The Company generated net revenue of \$1.3 million and \$3.9 million during the three and nine months ended September 30, 2019, respectively, and recorded related royalties of \$0.1 million and \$0.2 million during the three and nine months ended September 30, 2019, respectively. Royalty expense is included in operating expenses in the condensed consolidated statements of comprehensive loss. Accrued royalty of \$1.4 million and \$0.4 million as of September 30, 2020 and December 31, 2019, respectively, is included within accrued liabilities on the Company's condensed consolidated balance sheets.

### **Legal Matters**

On November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (collectively, the Medtronic Affiliates) filed an initial complaint against the Company in the United States District Court for the Central District of California, Case No. 8:19-cv-2115, and amended the complaint on November 26, 2019. The Company refers to this matter as the Medtronic Litigation. The complaint asserts that the Company's r-SNM System infringes U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324 and 9,821,112 held by the Medtronic Affiliates, and the amended complaint further includes the additional patents 8,738,148; 8,457,758; and 7,774,069 (collectively, the Medtronic Patents). The Medtronic Litigation requests customary remedies for patent infringement, including (i) a judgment that the Company has infringed and is infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) a permanent injunction preventing the Company from infringing the Medtronic Patents, (iv) attorneys' fees, and (v) costs and expenses. The Company believes the allegations are without merit and is vigorously defending itself against them. Given the early stage of the Medtronic Litigation, the Company is unable to predict the likelihood of success of the claims of the Medtronic Affiliates against the Company or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and require the Company to dedicate significant financial resources and management resources to its defense. An adverse ruling against the Company could materially and adversely affect its business, financial position, results of operations or cash flows and could also result in reputational harm. Even if

the Company is successful in defending against these claims, the Medtronic Litigation could result in significant costs, delays in future product developments, reputational harm or other collateral consequences.

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

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

#### **Note 4. Long-Term Debt**

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

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

In October 2018, the Company and Silicon Valley Bank entered into an amendment to the Loan Agreement (the Loan Amendment) in connection with which the Company requested the full \$5.0 million from Tranche B and the full \$5.0 million from Tranche C. The Company received the \$10.0 million from both tranches in October 2018. Pursuant to the Loan Amendment, Silicon Valley Bank agreed to (i) extend the interest only period from June 30, 2019 to December 31, 2019, without requiring the receipt of the Company’s PMA in the United States for the r-SNM System, and (ii) make Tranche C available immediately instead of January 1, 2019. In addition, as a result of the Company’s request of the full \$5.0 million from Tranche B and the full \$5.0 million from Tranche C, the maturity of the Term Loan has been automatically extended to December 1, 2021. The transaction was accounted for as a debt modification. See Note 5 for discussion regarding stock warrants granted in connection with the Term Loan.

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

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

All obligations under the Term Loan are secured by a first priority lien on substantially all of the Company's assets, excluding intellectual property assets and more than 65% of the shares of voting capital stock of any of its foreign subsidiaries. The Company has agreed with Silicon Valley Bank not to encumber its intellectual property assets without Silicon Valley Bank's prior written consent unless a security interest in the underlying intellectual property is necessary to have a security interest in the accounts and proceeds that are part of the assets securing the Term Loan, in which case the Company's intellectual property shall automatically be included within the assets securing the Term Loan. As of September 30, 2020, the Company was in compliance with all debt covenant requirements under the Term Loan.

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

	September 30, 2020	December 31, 2019
Debt, principal	\$ 20,000	\$ 20,000
Accrued loan fees	1,500	1,500
Debt, total	21,500	21,500
Less: unamortized debt issuance costs	(570)	(1,164)
Debt, net of unamortized debt issuance costs	20,930	20,336
Less: debt, current portion	(15,000)	—
Debt, net of unamortized debt issuance costs, net of current portion	\$ 5,930	\$ 20,336

#### Note 5. Stock-based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	\$ 882	\$ 477	\$ 2,493	\$ 1,170
General and administrative	1,448	1,267	4,726	2,688
Sales and marketing	1,445	1,038	4,294	1,941
	\$ 3,775	\$ 2,782	\$ 11,513	\$ 5,799

### Stock Option Activity

The option awards issued under the 2014 Stock Option Plan (the 2014 Plan) and the 2018 Omnibus Incentive Plan (the 2018 Plan) were measured based on fair value. The Company's fair value calculations were made using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Expected term (in years)	—	5.50 - 6.08	6.05	5.07 - 6.16
Stock volatility	—	71.22% - 73.76%	72.01%	70.02% - 73.76%
Risk-free interest rate	—	1.42% - 1.87%	1.37%	1.42% - 2.56%
Dividend rate	—	—	—	—

The Company used the simplified method of determining the expected term of stock options. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have sufficient trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments, whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The assumptions regarding the expected term of the options and the expected volatility of the stock price are subjective, and these assumptions have a significant effect on the estimated fair value amounts. There were no stock option grants for the three months ended September 30, 2020. The weighted-average grant date fair value of options granted was \$18.56 for the nine months ended September 30, 2020. The weighted-average grant date fair value of options granted was \$26.23 and \$15.75 for the three and nine months ended September 30, 2019, respectively.

As of September 30, 2020 and December 31, 2019, there was \$13.5 million and \$19.5 million, respectively, of total unrecognized compensation cost related to unvested stock options that is expected to be recognized over a weighted-average period of approximately 2.6 years and 3.2 years, respectively.

The following table summarizes stock option activity for the nine months ended September 30, 2020 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, 2019	2,847,101	\$ 13.22	
Options granted	5,000	29.03	
Options exercised	(665,369)	3.98	\$ 21,467 (1)
Options forfeited	(62,766)	25.46	
Outstanding at September 30, 2020	2,123,966	\$ 15.79	\$ 74,867 (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 the third quarter of 2020 and the stock option exercise price, multiplied by the number of in-the-money options as of September 30, 2020. The amount of intrinsic value will change based on the fair market value of the Company's stock.

The weighted-average remaining contractual term of options outstanding and exercisable is 7.8 years and 7.6 years at September 30, 2020 and December 31, 2019, respectively.

**Restricted Shares Awards Activity**

As of September 30, 2020 and December 31, 2019, there was \$19.8 million and \$11.8 million, respectively, of total unrecognized compensation cost related to unvested restricted shares awards that is expected to be recognized over a weighted-average period of approximately 3.2 years and 3.3 years, respectively.

The following table summarizes restricted shares awards activity for the nine months ended September 30, 2020:

	Number of Restricted Shares Awards	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2019	586,166	\$ 23.59
Restricted shares awards granted	371,250	34.22
Restricted shares awards vested	(137,609)	23.23
Restricted shares awards forfeited	(40,312)	25.33
Outstanding at September 30, 2020	779,495	\$ 28.63

**Restricted Stock Units Activity**

As of September 30, 2020 and December 31, 2019, there was \$1.9 million and \$4.3 million, respectively, of total unrecognized compensation cost related to unvested restricted stock units that is expected to be recognized over a weighted-average period of approximately 0.9 years and 1.5 years, respectively.

The following table summarizes restricted stock units activity for the nine months ended September 30, 2020:

	Number of Restricted Stock Units	Weighted-Average Fair Value Per Share at Grant Date
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
Outstanding at September 30, 2020	209,768	\$ 23.37

**Warrant Exercise**

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 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 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 September 30, 2020.

## **Note 6. Income Taxes**

The Company used an annual effective tax rate approach to calculate income taxes for the three and nine months ended September 30, 2020 and 2019. The annual effective tax rate of approximately 0% differs from the federal statutory tax rate due primarily to providing a full valuation allowance on net deferred tax assets.

At December 31, 2019, the Company had federal and California net operating loss (NOL) carryforwards of approximately \$162.5 million. Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code), use of the Company's NOL carryforwards may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a rolling three-year period. The Company has not performed an analysis of changes in ownership for purposes of these Internal Revenue Code sections. Ownership changes could impact the Company's ability to utilize NOL carryforwards remaining at an ownership change date. The Company's NOL carryforwards were generated from domestic operations. The federal NOLs from the 2013-2017 tax years will expire between 2033 and 2037 and NOLs from 2018-2019 will carryover indefinitely. The state NOLs will expire between 2033 and 2039. Under California Assembly Bill 85, effective June 29, 2020, net operating loss deductions were suspended for tax years beginning in 2019, 2020, and 2021 and the carry forward periods of any net operating losses not utilized due to such suspension were extended. At December 31, 2019, the Company also had research and development tax credit carryforwards of approximately \$2.0 million, which will expire in 2036 to 2039. Approximately \$0.9 million of these research and development tax credit carryforwards are included in prepaid expenses and other current assets on the Company's consolidated balance sheets at September 30, 2020 and December 31, 2019, as they are expected to be utilized in 2020 as a credit to offset payroll taxes. The remaining amount of research and development tax credit carryforwards are included in net deferred tax assets.

## **CARES Act**

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

## **Note 7. 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 three and nine months ended September 30, 2020, the Company contributions to the plan amounted to \$0.4 million and \$1.2 million, respectively. During the three and nine months ended September 30, 2019, the Company contributions to the plan amounted to and \$0.4 million and \$0.8 million, respectively.

## **Note 8. Related Party Transactions**

The Company has a License Agreement and corresponding royalties incurred with AMF, which is also a stockholder of the Company. For additional information, see Note 3.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q, as well as the audited consolidated financial statements and the related notes thereto, and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC on March 4, 2020.*

## Overview

We are a medical technology company that has developed and is commercializing innovative and minimally invasive implantable sacral neuromodulation (SNM) systems used to treat patients with urinary urge incontinence (UII) and urinary urgency frequency (UUF), together referred to as overactive bladder (OAB), fecal incontinence (FI), and non-obstructive urinary retention (UR).

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

We believe our proprietary rechargeable SNM system (r-SNM System) offers significant advantages, including being the first rechargeable SNM system marketed worldwide. It is designed to last approximately 15 years and is only 5cc in volume which is 60% smaller than Interstim II, marketed by Medtronic plc (Medtronic). We believe our r-SNM System has the potential to disrupt and grow the current approximately \$650 to \$700 million global SNM market, which has historically been served by Medtronic, as a single participant.

We have marketing approvals in Europe, Canada, and Australia for all relevant clinical indications and initiated limited commercial efforts in England, the Netherlands and Canada in late 2018. Revenue during the nine months ended September 30, 2020 from international operations in the Netherlands, England, Canada, Switzerland, Norway and Germany, was \$2.9 million.

On September 6, 2019, our premarket approval (PMA) application for our r-SNM System for the treatment of FI was approved by the U.S. Food and Drug Administration (FDA) and on November 13, 2019, our PMA application for our r-SNM System for the treatment of OAB and UR was approved by the FDA.

We have limited commercial activities outside the United States. Our main priority is the United States, which accounts for the vast majority of SNM sales worldwide. In the United States, we began to commercialize and market our r-SNM System in the fourth quarter of 2019. During the first half of 2019, we established a significant commercial infrastructure in advance of FDA approval of our r-SNM System and we continued to make significant investments to build our commercial organization by hiring dedicated full-time employees consisting of field-based sales and clinical personnel to market and support our product in the United States. We hired and trained sales representatives and clinical specialists with strong sales backgrounds and experience in SNM therapy and other neurostimulation applications, and with relationships with urologists and urogynecologists.

We began U.S. commercialization of our r-SNM System in November of 2019. By the end of the third quarter of 2020, over 600 unique accounts in the United States have implanted the Axonics r-SNM System.

Revenue during the nine months ended September 30, 2020 from accounts located across the United States was \$73.8 million.

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

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

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

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

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

Our ability to generate revenue and become profitable will depend on our ability to continue to successfully commercialize our r-SNM System and any product enhancements we may advance in the future. We expect to derive future revenue by increasing patient and physician awareness of our r-SNM System. If we are unable to accomplish any of these objectives, it could have a significant negative impact on our future revenue. If we fail to generate sufficient revenue in the future, our business, results of operations, financial condition, cash flows, and future prospects would be materially and adversely affected.

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

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

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

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

We incurred net losses of \$43.6 million and \$57.2 million for the nine months ended September 30, 2020 and 2019, respectively, and had an accumulated deficit of \$223.2 million as of September 30, 2020 compared to \$179.6 million at December 31, 2019. As of September 30, 2020, we had available cash and cash equivalents of approximately \$269.3 million, current liabilities of approximately \$38.8 million, and long-term liabilities of approximately \$15.0 million.

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

## **Impact of COVID-19**

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

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

## **AMF License Agreement**

On October 1, 2013, we entered into a license agreement (the License Agreement) with the Alfred E. Mann Foundation for Scientific Research (AMF), pursuant to which AMF licensed us certain patents and know-how (AMF IP), relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (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 nine months ended September 30, 2020 and 2019, we have recorded royalties of \$3.0 million and \$0.2 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 nine months ended September 30, 2020 from U.S. operations was \$73.8 million.

Revenue during the nine months ended September 30, 2020 and 2019 from international operations in the Netherlands, England, Canada, Switzerland, Norway and Germany, was \$2.9 million and \$3.9 million, respectively.

### ***Cost of Goods Sold and Gross Margin***

Cost of goods sold consists primarily of acquisition costs of the components of our r-SNM System, third-party contract labor costs, overhead costs, as well as distribution-related expenses such as logistics and shipping costs, net of costs charged to customers. The overhead costs include the cost of material procurement and operations supervision and management personnel. We expect overhead costs as a percentage of revenue to decrease as our sales volume increases. Cost of goods sold also include other expenses such as scrap and inventory obsolescence.

We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our revenue grows. We expect gross margin to vary based on regional differences in pricing and discounts negotiated by customers.

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

### **Research and Development Expenses**

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

The following table summarizes our research and development expenses by functional area for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Personnel related	\$ 3,273	\$ 3,175	\$ 8,072	\$ 8,432
Clinical development	107	213	292	1,108
Contract fabrication and manufacturing	1,643	244	4,043	1,469
Contract R&D and consulting	2,455	829	7,360	1,939
Other R&D expenses	270	394	1,263	1,000
Total R&D expenses	\$ 7,748	\$ 4,855	\$ 21,030	\$ 13,948

### **General and Administrative Expenses**

General and administrative expenses consist primarily of employee compensation, including stock-based compensation, and spending related to finance, information technology, human resource functions, consulting, legal, and professional service fees. Other general and administrative expenses include director and officer insurance premiums, investor relations costs, office-related expenses, facilities and equipment rentals, bad debt expense, and travel expenses. We expect our general and administrative expenses will 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 when we no longer qualify as an “emerging growth company” under the Jumpstart Our Business Startups (JOBS) Act, which will require us to comply with certain reporting requirements beginning with our 2020 annual report. We expect general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

### **Sales and Marketing Expenses**

Sales and marketing expenses consist primarily of employee compensation, including stock-based compensation, trade shows, booth exhibition costs, and the related travel for these events. Other sales and marketing

expenses include consulting and advisory fees. We expect sales and marketing expenses to continue to increase in absolute dollars as we expand our commercial infrastructure to both drive and support our expected growth in revenue. However, we expect sales and marketing expenses to decrease as a percentage of revenue in the long term primarily as, and to the extent, our revenue grows.

### **Other Income (Expense), Net**

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

### **Income Tax Expense**

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

### **Results of Operations**

The following table shows our results of operations for the three and nine months ended September 30, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended September 30,		Period to Period Change	Nine Months Ended September 30,		Period to Period Change
	2020	2019		2020	2019	
Net revenue	\$ 35,243	\$ 1,309	\$ 33,934	\$ 76,752	\$ 3,874	\$ 72,878
Cost of goods sold	13,434	632	12,802	31,792	1,952	29,840
Gross profit	21,809	677	21,132	44,960	1,922	43,038
Gross Margin	61.9 %	51.7 %		58.6 %	49.6 %	
<b>Operating Expenses</b>						
Research and development	7,748	4,855	2,893	21,030	13,948	7,082
General and administrative	5,773	5,162	611	18,963	13,539	5,424
Sales and marketing	17,057	15,707	1,350	47,846	32,371	15,475
Total operating expenses	30,578	25,724	4,854	87,839	59,858	27,981
Loss from operations	(8,769)	(25,047)	16,278	(42,879)	(57,936)	15,057
<b>Other Income (Expense)</b>						
Interest income	35	627	(592)	742	2,500	(1,758)
Interest and other expense	(434)	(586)	152	(1,429)	(1,747)	318
Other income (expense), net	(399)	41	(440)	(687)	753	(1,440)
Loss before income tax expense	(9,168)	(25,006)	15,838	(43,566)	(57,183)	13,617
Income tax expense	—	—	—	1	1	—
Net loss	(9,168)	(25,006)	15,838	(43,567)	(57,184)	13,617
Foreign currency translation adjustment	99	(112)	211	(186)	(165)	(21)
Comprehensive loss	\$ (9,069)	\$ (25,118)	\$ 16,049	\$ (43,753)	\$ (57,349)	\$ 13,596

### **Comparison of the Three Months Ended September 30, 2020 and 2019**

#### *Net Revenue*

Net revenue was \$35.2 million for the three months ended September 30, 2020 and was derived from the sale of our r-SNM Systems to customers in the United States, Europe and Canada. Net revenue was \$1.3 million for

the three months ended September 30, 2019 and was derived from the sale of our r-SNM System to customers in Europe and Canada. The increase in net revenue is primarily due to the commercial launch in the United States, partially offset by a decrease in sales in Europe and Canada as related to the COVID-19 pandemic.

*Cost of Goods Sold and Gross Margin*

We incurred \$13.4 million of cost of goods sold for the three months ended September 30, 2020. We incurred \$0.6 million of cost of goods sold for the three months ended September 30, 2019. Gross margin was 61.9% in the three months ended September 30, 2020, compared to 51.7% for the three months ended September 30, 2019. The increase in gross margin is primarily due to higher sales volume as well as the commercial launch in the United States, which has higher average sales prices.

*Research and Development Expenses*

Research and development expenses increased \$2.9 million, or 59.6%, to \$7.7 million in the three months ended September 30, 2020, compared to \$4.9 million in the three months ended September 30, 2019. The increase in research and development expenses was primarily attributable to an increase of \$1.6 million in contract research and development and consulting expenses and an increase of \$1.4 million in contract fabrication and manufacturing costs.

*General and Administrative Expenses*

General and administrative expenses increased \$0.6 million, or 11.9%, to \$5.8 million in the three months ended September 30, 2020, compared to \$5.2 million in the three months ended September 30, 2019, primarily as a result of an increase of \$0.2 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits and an increase of \$0.2 million in rent expense.

*Sales and Marketing Expenses*

Sales and marketing expenses increased \$1.4 million, or 8.6%, to \$17.1 million in the three months ended September 30, 2020, compared to \$15.7 million in the three months ended September 30, 2019. The increase in sales and marketing expenses was primarily due to an increase of \$2.6 million related to personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, partially offset by decrease of \$0.7 million in travel expenses.

*Other Income (Expense), Net*

Other expense, net was \$0.4 million in the three months ended September 30, 2020 consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank, partially offset by interest income earned on cash equivalents. Other income, net was minimal in the three months ended September 30, 2019.

*Income Tax Expense*

We recorded no income tax expense for the three months ended September 30, 2020 and 2019.

**Comparison of the Nine Months Ended September 30, 2020 and 2019**

*Net Revenue*

Net revenue was \$76.8 million for the nine months ended September 30, 2020 and was derived from the sale of our r-SNM Systems to customers in the United States, Europe and Canada. Net revenue was \$3.9 million for the nine months ended September 30, 2019 and was derived from the sale of our r-SNM System to customers in Europe and Canada. The increase in net revenue is primarily due to the commercial launch in the United States, partially offset by a decrease in sales in Europe and Canada as related to the COVID-19 pandemic.

*Cost of Goods Sold and Gross Margin*

We incurred \$31.8 million of cost of goods sold for the nine months ended September 30, 2020. We incurred \$2.0 million of cost of goods sold for the nine months ended September 30, 2019. Gross margin was 58.6% in the nine months ended September 30, 2020, compared to 49.6% for the nine months ended September 30, 2019. The increase in gross margin is primarily due to higher sales volume as well as the commercial launch in the United States, which has higher average sales prices.

#### *Research and Development Expenses*

Research and development expenses increased \$7.1 million, or 50.8%, to \$21.0 million in the nine months ended September 30, 2020, compared to \$13.9 million in the nine months ended September 30, 2019. The increase in research and development expenses was primarily attributable to an increase of \$5.4 million in contract research and development and consulting expenses and an increase of \$2.6 million in contract fabrication and manufacturing costs, partially offset by a decrease of \$0.8 million in clinical development costs to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions.

#### *General and Administrative Expenses*

General and administrative expenses increased \$5.4 million, or 40.1%, to \$19.0 million in the nine months ended September 30, 2020, compared to \$13.5 million in the nine months ended September 30, 2019, primarily as a result of an increase of \$2.2 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, an increase of \$1.4 million in legal and consulting costs, an increase of \$0.8 million in rent expense, and an increase of \$0.4 million in bad debt expense.

#### *Sales and Marketing Expenses*

Sales and marketing expenses increased \$15.5 million, or 47.8%, to \$47.8 million in the nine months ended September 30, 2020, compared to \$32.4 million in the nine months ended September 30, 2019. The increase in sales and marketing expenses was primarily due to an increase of \$17.5 million related to personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, partially offset by a decrease of \$1.6 million in travel expenses.

#### *Other Income (Expense), Net*

Other expense, net was \$0.7 million in the nine months ended September 30, 2020 consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank, partially offset by interest income earned on cash equivalents. Other income, net was \$0.8 million in the nine months ended September 30, 2019 consisting primarily of interest income earned on cash equivalents and short-term investments, partially offset by interest expense incurred related to the Loan Agreement with Silicon Valley Bank.

#### *Income Tax Expense*

We recorded minimal income tax expense for the nine months ended September 30, 2020 and 2019, respectively.

### **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 \$43.6 million and \$57.2 million for the nine months ended September 30, 2020 and 2019, respectively, and had an accumulated deficit of \$223.2 million as of September 30, 2020 compared to \$179.6 million at December 31, 2019. We expect to continue to spend a significant amount of our existing resources on sales and marketing activities as we continue to commercialize and market our r-SNM System in the United States.

As of September 30, 2020, we had cash, cash equivalents and short-term investments of \$269.3 million compared to \$183.7 million at December 31, 2019. We expect that our cash, cash equivalents and short-term investments on hand will be sufficient to fund our operations through at least the next 12 months. We fund our operations through a combination of proceeds from public offerings of our common stock, cash receipts from sales of our r-SNM System and proceeds from our Loan Agreement with Silicon Valley Bank. As of September 30, 2020, we had \$21.5 million in outstanding borrowings, as discussed below under "Indebtedness." If we raise additional funds by issuing equity securities, our stockholders could experience dilution. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain

additional financing when needed to satisfy our liquidity requirements, we may be required to scale back our operations.

### Cash Flows

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

	Nine Months Ended September 30,	
	2020	2019
Net cash provided by (used in)		
Operating activities	\$ (55,428)	\$ (55,318)
Investing activities	10,677	32,945
Financing activities	143,135	463
Effect of exchange rate changes on cash and cash equivalents	(186)	(165)
Net increase (decrease) in cash and cash equivalents	<u>\$ 98,198</u>	<u>\$ (22,075)</u>

#### *Net cash used in operating activities*

Net cash used in operating activities was \$55.4 million for the nine months ended September 30, 2020 and consisted primarily of a net loss of \$43.6 million and a decrease in net operating assets of \$25.8 million, partially offset by non-cash charges of \$13.9 million. Net operating assets consisted primarily of accounts receivable and inventory due to 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 \$55.3 million for the nine months ended September 30, 2019 and consisted primarily of a net loss of \$57.2 million and a decrease in net operating assets of \$5.5 million, partially offset by non-cash charges of \$7.3 million. Net operating assets consisted primarily of inventory to support the anticipated commercial launch of our r-SNM System in the United States. Non-cash charges consisted primarily of stock-based compensation.

#### *Net cash provided by investing activities*

Net cash provided by investing activities was \$10.7 million for the nine months ended September 30, 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 \$32.9 million for the nine months ended September 30, 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 \$143.1 million for the nine months ended September 30, 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 \$0.5 million for the nine months ended September 30, 2019 and consisted of proceeds from exercise of stock options.

### Indebtedness

In February 2018, we entered into a Loan and Security Agreement with Silicon Valley Bank, which we and Silicon Valley Bank amended in October 2018 and in December 2019, providing for the Term Loan. Pursuant to the Loan Agreement, we have drawn \$20.0 million in three tranches of term loans, with such drawn obligations maturing on December 1, 2021.

The Loan Agreement provides for monthly interest payments but no principal amortization through December 31, 2020. On the first day of the end of the interest only period, we will be required to repay the Term

Loan in equal monthly installments of principal plus interest through maturity. Outstanding principal balances under the Term Loan bear interest at the prime rate plus 1.75%.

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

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

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

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

As of September 30, 2020, we were in compliance with all debt covenant requirements under the Term Loan. While we have not previously breached and are currently in compliance with the covenants contained in the Loan Agreement, we may breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, Silicon Valley Bank may choose to declare an event of default and require that we immediately repay all amounts outstanding under the Loan Agreement, terminate any commitment to extend further credit and foreclose on the collateral. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations. An event of default includes, but is not limited to, the following: if we fail to make any payment under the Loan Agreement when due, if we fail or neglect to perform certain obligations under the Loan Agreement, if we violate certain covenants under the Loan Agreement, if certain material adverse changes occur, if we are unable to pay our debts as they become due or otherwise become insolvent, or if we begin an insolvency proceeding.

We have no further indebtedness arrangements.

#### **Off-Balance Sheet Arrangements**

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

### **Contractual Obligations**

As a smaller reporting company, we are not required to provide the information required by Item 303(a)(5) of Regulation S-K.

### **Critical Accounting Policies and Estimates**

Our critical accounting policies and estimates are described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC on March 4, 2020. We have reviewed and determined that those critical accounting policies and estimates remain our critical accounting policies and estimates as of and for the nine months ended September 30, 2020.

### **Recent Accounting Pronouncements**

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 1 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, such standards will not have a significant impact on our condensed consolidated financial statements or do not otherwise apply to our operations.

### **Item 3. Quantitative and Qualitative Disclosure About Market Risk.**

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

### **Item 4. 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 the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2020.

#### ***Changes in internal control over financial reporting***

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II—OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

On November 4, 2019, Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (collectively, the Medtronic Affiliates) filed an initial complaint against us in the United States District Court for the Central District of California, Case No. 8:19-cv-2115, and amended the complaint on November 26, 2019. We refer to this matter as the Medtronic Litigation. The complaint asserts that our r-SNM System infringes U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324 and 9,821,112 held by the Medtronic Affiliates, and the amended complaint further includes the additional patents 8,738,148; 8,457,758; and 7,774,069 (collectively, the Medtronic Patents). The Medtronic Litigation requests customary remedies for patent infringement, including (i) a judgment that we have infringed and are infringing the Medtronic Patents, (ii) damages, including treble damages for willful infringement, (iii) a permanent injunction preventing us from infringing the Medtronic Patents, (iv) attorneys' fees, and (v) costs and expenses. We believe the allegations are without merit and are vigorously defending ourselves against them. Given the early stage of the Medtronic Litigation, we are unable to predict the likelihood of success of the claims of the Medtronic Affiliates against us or to quantify any risk of loss. The Medtronic Litigation could last for an extended period of time and require us to dedicate significant financial resources and management resources to our defense. An adverse ruling against us could materially and adversely affect our business, financial position, results of operations or cash flows and could also result in reputational harm. Even if we are successful in defending against these claims, the Medtronic Litigation could result in significant costs, delays in future product developments, reputational harm or other collateral consequences.

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

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

### **Item 1A. Risk Factors.**

You should carefully consider the information described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC on March 4, 2020. There have been no material changes from the risk factors disclosed in our recent SEC filings, including our most recently filed Form 10-K, as referenced above, except as follows:

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

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries and all 50 states within the United States. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by significantly decreasing and delaying the number of procedures performed using our r-SNM System, and we expect the pandemic to continue to negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our r-SNM System has decreased significantly as healthcare organizations in the United States and globally, including in Europe and Canada have prioritized the treatment of patients with COVID-19 or have altered their operations to prepare for and respond to the pandemic. For example, in the United States, governmental authorities have recommended, and in certain cases required, or healthcare providers have decided that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. We believe the COVID-19 pandemic

has also negatively impacted the number of OAB, FI and UR diagnoses and patients screened for eligibility for our r-SNM system as hospitals and ambulatory surgery centers focus on COVID-19 and as patients postpone healthcare visits and treatments. Specifically, substantially all of the procedures using our r-SNM System were postponed or cancelled from middle of March 2020 through May 2020, but order flow began a gradual recovery in May 2020 and continued to improve through the third quarter of 2020. Many areas in the United States have since restarted procedures with our r-SNM System, but the situation is evolving rapidly and remains uncertain due to recent increases in COVID-19 cases and related hospitalizations. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will continue to significantly reduce our revenue and negatively impact our business, financial condition and results of operations while the pandemic continues. Further, once the pandemic subsides, we anticipate there will be a substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers relating to a variety of medical conditions, and as a result, patients seeking procedures performed using our r-SNM System, may have to navigate limited provider capacity. We believe this limited provider, hospital and ambulatory surgery center capacity could have a significant adverse effect on our business, financial condition and results of operations following the end of the pandemic. Additionally, even after it is deemed advisable to resume conducting elective procedures, some patients may elect not to undergo procedures or delay scheduling procedures to avoid traveling to healthcare facilities due to safety concerns.

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

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

other risks described in the “Risk Factors” section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC on March 4, 2020, including those relating to incurring future operating losses, dependence of the r-SNM System, successful commercialization, supply chain and distribution channels.

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

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

We consider our primary competition to be other implantable SNM devices. We face competition from major medical device companies worldwide, including Medtronic, the maker of InterStim II and InterStim Micro. InterStim II and InterStim Micro are currently the only other implantable SNM device 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.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

**Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Title</b>
31.1	<a href="#">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.</a>
31.2	<a href="#">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.</a>
32.1#	<a href="#">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.</a>
32.2#	<a href="#">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.</a>
101.INS**	Inline XBRL Instance Document.
101.SCH**	Inline XBRL Taxonomy Extension Schema Document.
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101).

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 Quarterly Report on Form 10-Q), 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 Quarterly Report on Form 10-Q 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.



I, Raymond W. Cohen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Axonics Modulation Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2020

By:

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

I, Dan L. Dearen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Axonics Modulation Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2020

By:

/s/ Dan L. Dearen

Dan L. Dearen

*President and Chief Financial Officer  
(Principal Financial Officer)*

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 Quarterly Report of Axonics Modulation Technologies, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2020

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

*Chief Executive Officer and Director*  
*(Principal Executive Officer)*

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

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 Quarterly Report of Axonics Modulation Technologies, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2020

By:

/s/ Dan L. Dearen

Dan L. Dearen

*President and Chief Financial Officer*

*(Principal Financial Officer)*

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