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, 2019

or

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

For the transition period from _____ to _____

Commission File Number: 001-38721

Axonics Modulation Technologies, Inc.

(Exact name of registrant as specified in its charter)

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

(949) 396-6322

(Registrant's telephone number, including area code)

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 o

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 o

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	o	Accelerated filer	o
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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

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

As of November 13, 2019, 28,602,766 shares of the registrant's common stock, par value $0.0001 per share, were outstanding.

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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:

- announcements of regulatory approval or disapproval of our proprietary rechargeable sacral neuromodulation ("SNM") system ("r-SNM System") and any future enhancements to our r-SNM System;
- adverse results from or delays in clinical studies of our r-SNM System;
- unanticipated safety concerns related to the use of our r-SNM System;
- U.S. Food and Drug Administration ("FDA") or other U.S. or foreign regulatory or legal actions or changes affecting us or our 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;
- 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;
- intellectual property, product liability or other litigation against us, our third-party manufacturers or other parties on which we rely or litigation against our general industry;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- the results of any future legal proceedings.

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. This Quarterly Report on Form 10-Q also includes trademarks and trade names that are the property of other organizations. 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, 2019	December 31, 2018
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 76,231	$ 98,306
Short-term investments	25,311	59,218
Accounts receivable	954	427
Inventory, net	12,703	3,673
Prepaid expenses and other current assets	2,625	3,716
Total current assets	117,824	165,340
Property and equipment, net	2,952	2,784
Intangible asset, net	340	426
Other assets	4,928	3,356
Total assets	$ 126,044	$ 171,906
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 4,232	$ 3,436
Accrued liabilities	4,304	1,683
Lease liability, current portion	625	768
Debt, net of unamortized debt issuance costs, current portion	6,382	—
Total current liabilities	15,543	5,887
Lease liability, net of current portion	4,573	3,281
Debt, net of unamortized debt issuance costs, net of current portion	13,740	19,463
Total liabilities	33,856	28,631
Stockholders' equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, par value $0.0001, 50,000,000 shares authorized at September 30, 2019 and December 31, 2018; 28,633,911 and 27,806,934 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	3	3
Additional paid-in capital	249,599	243,337
Accumulated deficit	(156,833)	(99,649)
Accumulated other comprehensive loss	(581)	(416)
Total stockholders' equity	92,188	143,275
Total liabilities and stockholders' equity	$ 126,044	$ 171,906

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,	
	2019	2018	2019	2018
Net revenue	$ 1,309	$ 201	$ 3,874	$ 213
Cost of goods sold	632	106	1,952	111
Gross profit	677	95	1,922	102
Operating Expenses				
Research and development	4,855	3,898	13,948	14,619
General and administrative	5,162	2,790	13,539	5,861
Sales and marketing	15,707	949	32,371	2,308
Total operating expenses	25,724	7,637	59,858	22,788
Loss from operations	(25,047)	(7,542)	(57,936)	(22,686)
Other Income (Expense)				
Interest income	627	172	2,500	448
Interest and other expense	(586)	(196)	(1,747)	(579)
Other income (expense), net	41	(24)	753	(131)
Loss before income tax expense	(25,006)	(7,566)	(57,183)	(22,817)
Income tax expense	—	—	1	1
Net loss	(25,006)	(7,566)	(57,184)	(22,818)
Foreign currency translation adjustment	(112)	(1)	(165)	(4)
Comprehensive loss	$ (25,118)	$ (7,567)	$ (57,349)	$ (22,822)
Net loss per share, basic and diluted (see Note 1)	$ (0.89)	$ (2.67)	$ (2.05)	$ (8.10)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	28,098,564	2,830,591	27,958,376	2,817,652

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock		Additional Paid-in		Accumulated Other	
	Shares	Amount	Capital	Accumulated Deficit	Comprehensive Loss	Total
Balance at December 31, 2018	27,806,934	$ 3	$ 243,337	$ (99,649)	$ (416)	$ 143,275
Issuance of common stock for employee stock option exercises for cash	41,740	—	44	—	—	44
Restricted Shares Award ("RSA") and stock option issuances and forfeitures for terminations, net	352,417	—	977	—	—	977
Restricted Stock Units ("RSU") issuances and forfeitures for terminations, net	—	—	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 and stock option issuances and forfeitures for terminations, net	112,417	—	1,629	—	—	1,629
RSU issuances and forfeitures for terminations, net	—	—	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 and stock option issuances and forfeitures for terminations, net	37,883	—	2,534	—	—	2,534
RSU issuances and forfeitures for terminations, net	—	—	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

	Common Stock		Additional Paid-in	Stock Subscriptions		Accumulated Other Comprehensive	
	Shares	Amount	Capital	Receivable	Accumulated Deficit	Loss	Total
Balance at December 31, 2017	2,776,583	$ —	$ 2,900	$ (1,753)	$ (67,166)	$ (402)	$ (66,421)
Issuance of common stock for employee stock option exercises for promissory notes	39,720	—	56	(56)	—	—	—
Stock option issuances and forfeitures for terminations, net	—	—	68	—	—	—	68
Foreign currency translation adjustment	—	—	—	—	—	(1)	(1)
Net loss	—	—	—	—	(6,604)	—	(6,604)
Balance at March 31, 2018	2,816,303	—	3,024	(1,809)	(73,770)	(403)	(72,958)
Issuance of common stock for employee stock option exercises for promissory notes	9,000	—	15	(15)	—	—	—
Stock option issuances and forfeitures for terminations, net	—	—	190	—	—	—	190
Foreign currency translation adjustment	—	—	—	—	—	(2)	(2)
Net loss	—	—	—	—	(8,648)	—	(8,648)
Balance at June 30, 2018	2,825,303	—	3,229	(1,824)	(82,418)	(405)	(81,418)
Issuance of common stock for employee stock option exercises for cash	5,288	—	6	—	—	—	6
Stock option issuances and forfeitures for terminations, net	—	—	101	—	—	—	101
Foreign currency translation adjustment	—	—	—	—	—	(1)	(1)
Net loss	—	—	—	—	(7,566)	—	(7,566)
Balance at September 30, 2018	2,830,591	$ —	$ 3,336	$ (1,824)	$ (89,984)	$ (406)	$ (88,878)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash Flows from Operating Activities		
Net loss	$ (57,184)	$ (22,818)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	880	663
Stock-based compensation	5,799	359
Amortization of debt issuance costs	659	146
Changes in operating assets and liabilities		
Accounts receivable	(527)	(219)
Inventory	(9,030)	(607)
Prepaid expenses and other current assets	1,091	(911)
Other assets	(327)	(120)
Accounts payable	796	367
Accrued liabilities	2,621	1,143
Lease liability	(96)	(77)
Net cash used in operating activities	(55,318)	(22,074)
Cash Flows from Investing Activities		
Purchases of property and equipment	(962)	(1,006)
Purchases of short-term investments	(35,210)	(23,029)
Proceeds from sales and maturities of short-term investments	69,117	12,100
Net cash provided by (used in) investing activities	32,945	(11,935)
Cash Flows from Financing Activities		
Payment of debt issuance costs	—	(142)
Proceeds from debt	—	10,000
Proceeds from exercise of stock options	463	6
Proceeds from issuance of preferred stock and noncontrolling interest	—	20,098
Payment of preferred stock issuance costs	—	(199)
Net cash provided by financing activities	463	29,763
Effect of exchange rate changes on cash and cash equivalents	(165)	(4)
Net decrease in cash and cash equivalents	(22,075)	(4,250)
Cash and cash equivalents, beginning of year	98,306	24,398
Cash and cash equivalents, end of period	$ 76,231	$ 20,148
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ 1,097	$ 393
Cash paid for taxes	$ 1	$ 1
Noncash Investing and Financing Activities		
Common stock issuance on stock option exercises for promissory notes	$ —	$ 71
Warrants issued as debt issuance costs	$ —	$ 240
Accrued loan fees as debt issuance costs	$ —	$ 750

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 an innovative and minimally invasive implantable neurostimulation system. 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 Europe, Canada, and Australia for OAB, UR, and FI. On September 6, 2019, our 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, our PMA application for the r-SNM System for the treatment of OAB and UR was approved by the FDA. Through September 30, 2019, the Company has 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.

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 financial statements and related footnote disclosures as of and for the three and nine months ended September 30, 2019 is unaudited, and is 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, 2019 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, 2018 (filed with the SEC on March 5, 2019).

Stock Split and Charter Amendment

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

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

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, 2019 and September 30, 2018 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. Effective January 1, 2018, the Company early adopted the comprehensive new revenue recognition standard using the modified retrospective method. As the Company generated minimal revenue through the date of adoption, the adoption of this guidance did not have a material impact on the Company's consolidated financial statements or related disclosures.

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 its product sales. The Company also does not have significant contract acquisition costs related to its product sales. The Company's revenue during the three and nine months ended September 30, 2019 and September 30, 2018 consisted primarily of sales to customers in Europe and Canada.

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, 2019 and September 30, 2018.

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

The following table presents the fair value hierarchy for those assets measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018 (in thousands):

	Fair Value Measurements at September 30, 2019			
Assets:	**Level 1**	**Level 2**	**Level 3**	**Total**
Commercial paper	$ —	$ 16,144	$ —	$ 16,144
Corporate notes	2,009	—	—	2,009
U.S. government and agency securities	7,158	—	—	7,158
	$ 9,167	$ 16,144	$ —	$ 25,311

	Fair Value Measurements at December 31, 2018			
Assets:	**Level 1**	**Level 2**	**Level 3**	**Total**
Commercial paper	$ —	$ 32,163	$ —	$ 32,163
Corporate notes	12,606	3,156	—	15,762
U.S. government and agency securities	11,293	—	—	11,293
	$ 23,899	$ 35,319	$ —	$ 59,218

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, 2019 and December 31, 2018, all foreign currency translation gains (losses) have been unrealized and included in accumulated other comprehensive loss. Accumulated other comprehensive loss consists entirely of losses from translation of foreign subsidiaries at September 30, 2019 and December 31, 2018. 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 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, 2019, the Company had $3.5 million, $2.5 million and $6.7 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, on hand. As of December 31, 2018, the Company had $0.9 million and $2.7 million of finished goods inventory and raw materials inventory, respectively, on hand. As of December 31, 2018, there were minimal work-in-process inventory on hand.

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 $0.7 million and $0.6 million at September 30, 2019 and December 31, 2018, respectively. The Company recorded expense for the amortization of intangible assets of $0.1 million during the nine months ended September 30, 2019 and 2018. The amortization of intangible assets were minimal during the three months ended September 30, 2019 and 2018. 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.

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.

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, 2019 and December 31, 2018, the remaining lease terms for all of the Company's operating leases were 8.1 years and 6.6 years, respectively. The discount rate used to determine the present value of all of the Company's operating leases' future payments was 7.25% (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 maintain 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 services in exchange for an award of equity instruments based on the grant-date fair value of the award and recognizes compensation cost over the requisite service period (typically the vesting period), generally four years. The Company accounts for equity instruments issued to non-employees based on the fair value of the award, which is periodically re-measured as they vest over the performance period. The related expense is recognized over the performance period. 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. The Company uses the Monte Carlo valuation model to value equity awards (as of the date of grant) that have combined market conditions and service conditions for vesting.

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, 2019, there were 2,286,802 and 1,812,578 potentially dilutive shares, respectively, that were not included in the computation of diluted weighted-average shares of common

stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss. For the three and nine months ended September 30, 2018, there were 14,422,173 and 13,805,246 potentially dilutive shares, respectively, that were not included in the computation of diluted weighted-average shares of common stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss.

Recent Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting", which expands guidance on accounting for share-based payment awards, which includes share-based payment transactions for acquiring goods and services from nonemployees and aligns the accounting for share-based payments for employees and non-employees. This guidance is effective for annual periods beginning after December 15, 2018, which was the Company's first quarter of fiscal year 2019, with early adoption permitted. The guidance should be applied to new awards granted after the date of adoption. The adoption of this guidance did not have an impact on the Company's consolidated financial statements or related disclosures.

Note 2. Property and Equipment

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

	September 30, 2019	December 31, 2018
Research and development equipment	$ 1,042	$ 885
Computer hardware and software	1,210	811
Tools and molds	1,285	1,110
Leasehold improvements	1,500	1,500
Furniture and fixtures	622	462
Construction in progress	71	—
	5,730	4,768
Less: accumulated depreciation and amortization	(2,778)	(1,984)
	$ 2,952	$ 2,784

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. Depreciation and amortization expense of property and equipment was $0.2 million and $0.6 million for the three and nine months ended September 30, 2018, respectively.

Note 3. Commitments

Operating Leases

In August 2014, the Company entered into a five-year operating lease for approximately 12,215 square feet of office space beginning on November 1, 2014, and expiring on October 31, 2019. In June 2019, the lease was amended to extend the expiration date to October 31, 2020. 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. 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 a new lease amendment (the "Lease") with its current landlord, The Irvine Company, LLC, for the lease of approximately 32,621 square feet of office space of a building located in Irvine, California. The Company intends to use the premises as its new principal executive offices and for general office. The Company intends to utilize its other currently-leased spaces through the lease expiration dates to conduct the training of its sales team and for manufacturing purposes.

Unless earlier terminated, the term of the Lease (the "Initial Term") will expire on the final day of the calendar month following the eighth anniversary of the commencement date. The commencement date is expected to be February 1, 2020. The Company does not control the leased premises before the expected commencement date. The aggregate base rent due over the Initial Term under the terms of the Lease is approximately $7.4 million (without giving effect to certain rent abatement terms). The Company will also be responsible for the payment of additional rent to cover certain costs, taxes, and insurance. Based on the estimated monthly additional rent for 2019 as set forth in the Lease, the Company estimates that the additional rent during the Initial Term will be approximately $1.9 million. The Company also expects to pay approximately $0.2 million for leasehold improvements, net of the tenant improvement allowance provided in the Lease of approximately $2.3 million.

The Company has a renewal option to extend the term of the Lease for a period of five years (the "Renewal Term") beyond the Initial Term. Under the terms of the Lease, the base rent payable with respect to each Renewal Term will be equal to the prevailing market rental rent as of the commencement of the applicable Renewal Term. In the event of a default of certain of the Company's obligations under the Lease, the Company's landlord would have the right to terminate the Lease. The Company is assessing the accounting impact of the Lease.

As of September 30, 2019 and December 31, 2018, the ROU asset has a balance of $4.3 million and $3.1 million, respectively. The operating lease ROU asset is included within the Company's other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company's condensed consolidated balance sheets. 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. During the three and nine months ended September 30, 2018, cash paid for amounts included in operating lease liabilities were $0.2 million and $0.3 million, 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. Amortization of the ROU asset was $0.1 million for the three and nine months ended September 30, 2018.

As of September 30, 2019 and December 31, 2018, the remaining lease term for all of the Company's operating leases were 8.1 years and 6.6 years, respectively. The discount rate used to determine the present value of all of the Company's operating leases' future payments was 7.25%.

Rent expense for the three and nine months ended September 30, 2019 was $0.4 million and $1.0 million, respectively. Rent expense for the three and nine months ended September 30, 2018 was $0.2 million and $0.4 million, respectively.

License Agreement

In October 2013, the Company entered into the License Agreement with AMF, pursuant to which AMF agreed to license to the Company certain patents and know-how (collectively, the "AMF IP") relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (collectively, the "AMF Licensed Products"). Pursuant to the License Agreement, AMF granted to the Company a royalty-bearing, sublicensable (by written, executed agreements only, subject to the terms of the License Agreement) license under the AMF IP to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of (i) chronic pain in humans through the application of electrical energy to the nervous system, (ii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve, a nerve that interfaces with parasympathetic control of the heart, lungs and digestive tract, and (iii) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the

cranial cavity or to the ocular nervous system or the auditory nervous system. Pursuant to the License Agreement, the Company is obligated to pay a 4% royalty of all net revenue derived from the AMF Licensed Products if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to the Company by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case, subject to certain adjustments. The initial term of the License Agreement is from October 1, 2013 to October 1, 2033, and will automatically continue until all patents are no longer in force. Since 2018, the Company has been required to pay a minimum annual royalty under the License Agreement. The minimum amount was $75,000 for 2018, with an increase in subsequent years of $25,000 (i.e., $100,000 for 2019) up to a maximum of $200,000 per year. The Company generated net revenue of $1.3 million and $3.9 million during the three and nine months ended September 30, 2019, and recorded related royalties of $0.1 million and $0.2 million during the three and nine months ended September 30, 2019, respectively. The Company generated net revenue of $0.2 million during each of the three and nine months ended September 30, 2018, and recorded minimal related royalties during the three and nine months ended September 30, 2018.

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

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

In October 2018, the Company and Silicon Valley Bank entered into an amendment to the Loan Agreement (the "Loan Amendment") in connection with which the Company requested the full $5.0 million from Tranche B and the full $5.0 million from Tranche C. The Company received the $10.0 million from both tranches in October 2018. Pursuant to the Loan Amendment, Silicon Valley Bank agreed to (i) extend the interest only period from June 30, 2019 to December 31, 2019, without requiring the receipt of the Company's PMA in the United States for the r-SNM System, and (ii) make Tranche C available immediately instead of January 1, 2019. In addition, pursuant to the Loan Amendment, Silicon Valley Bank added a fee of $100,000 in the event that the Company did not (i) consummate the IPO, with proceeds of no less than $75.0 million, (ii) receive PMA approval in the United States for the r-SNM System, or (iii) receive gross proceeds of at least $40.0 million from the sale of equity securities, in each case on or prior to June 30, 2019, which will not be owed since the Company completed the IPO offering in October 2018. 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.

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. At September 30, 2019, 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, 2019	December 31, 2018
Debt, principal	$ 20,000	$ 20,000
Accrued loan fees	1,500	1,500
Debt, total	21,500	21,500
Less: unamortized debt issuance costs	(1,378)	(2,037)
Debt, net of unamortized debt issuance costs	20,122	19,463
Less: debt, net of unamortized debt issuance costs, current portion	(6,382)	—
Debt, net of unamortized debt issuance costs, net of current portion	$ 13,740	$ 19,463

Note 5. Stock-based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 477	$ 44	$ 1,170	$ 141
General and administrative	1,267	55	2,688	211
Sales and marketing	1,038	2	1,941	7
	$ 2,782	$ 101	$ 5,799	$ 359

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,	
	2019	**2018**	**2019**	**2018**
Expected term (in years)	5.50 - 6.08	5.00 - 6.96	5.07 - 6.16	5.00 - 6.96
Stock volatility	71.22% - 73.76%	76.01% - 77.03%	70.02% - 73.76%	76.01% - 77.03%
Risk-free interest rate	1.42% - 1.87%	2.26% - 2.81%	1.42% - 2.56%	2.26% - 2.81%
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. 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. The weighted-average grant date fair value of options granted was $1.32 for the three and nine months ended September 30, 2018.

As of September 30, 2019 and December 31, 2018, there was $17.0 million and $2.2 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 3.2 years and 2.5 years, respectively.

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

	Number of Options	Weighted-Average Exercise Price Per Share	Aggregate Intrinsic Value	
Outstanding at December 31, 2018	1,514,347	$ 2.22		
Options granted	1,427,607	20.51		
Options exercised	(260,660)	1.77	$ 2,843	(1)
Options forfeited	(49,528)	12.78		
Outstanding at September 30, 2019	2,631,766	$ 11.98	$ 41,761	(2)

(1) Represents the total difference between our 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 our closing stock price on the last trading day of the third quarter of 2019 and the stock option exercise price, multiplied by the number of in-the-money options as of September 30, 2019. The amount of intrinsic value will change based on the fair market value of our stock.

The weighted-average remaining contractual term of options outstanding and exercisable is 7.8 years and 8.4 years at September 30, 2019 and December 31, 2018, respectively.

Restricted Shares Awards Activity

As of September 30, 2019 and December 31, 2018, there was $9.8 million and $0.4 million, respectively, of total unrecognized compensation cost related to unvested restricted shares awards that is expected to be recognized over a weighted-average period of approximately 3.3 years and 3.8 years, respectively.

The following table summarizes restricted shares awards activity:

	Number of Restricted Shares Awards	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2018	50,000	$ 14.48
Restricted shares awards granted	466,667	23.52
Restricted shares awards vested	(18,801)	20.87
Restricted shares awards forfeited	(13,950)	21.18
Outstanding at September 30, 2019	483,916	$ 22.76

Restricted Stock Units Activity

As of September 30, 2019, there was $0.7 million of total unrecognized compensation cost related to unvested restricted stock units that is expected to be recognized over a weighted-average period of approximately 1.0 year.

The following table summarizes restricted stock units activity:

	Number of Restricted Stock Units	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2018	—	$ —
Restricted stock units granted	92,672	14.19
Outstanding at September 30, 2019	92,672	$ 14.19

Warrant Exercise

On July 16, 2019, we issued and sold 32,529 shares of our common stock to SVB Financial Group (“SVB”) in connection with the exercise by SVB of its right to purchase 40,000 shares of our 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, we issued and sold 31,071 shares of our 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 our 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.

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, 2019 and 2018. 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, 2018, the Company had federal and California net operating loss ("NOL") carryforwards of approximately $63.4 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. NOLs expire between 2034 and 2038. At December 31, 2018, the Company also had research and development tax credit carryforwards of approximately $2.3 million, which will expire in 2036 to 2038. Approximately $0.6 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, 2019 and December 31, 2018, as they are expected to be utilized in 2019 as a credit to offset payroll taxes. The remaining amount of research and development tax credit carryforwards are included in net deferred tax assets.

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, 2019, the Company contributions to the plan amounted to $0.4 million and $0.8 million, respectively. During the three and nine months ended September 30, 2018, the Company contributions to the plan amounted to $0.1 million and $0.2 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. John Petrovich, a former member of the Company's board of directors is the President, Chief Executive Officer, Senior Vice President, Business Development, and General Counsel of AMF. For additional information, see Note 3.

The Company incurred no amount and minimal amounts during the three and nine months ended September 30, 2019, respectively, and minimal amounts and $0.1 million during the three and nine months ended September 30, 2018, respectively, to a scientific advisor who is also a non-management stockholder of the Company. There were no amounts payable to this advisor at September 30, 2019. Amounts payable to this advisor were minimal at December 31, 2018.

The Company incurred minimal amounts and $0.1 million during the three and nine months ended September 30, 2019, respectively, and $0.1 million and $0.3 million during the three and nine months ended September 30, 2018, respectively, for engineering and design services to a company that is owned by a non-management stockholder of the Company. There were no amounts payable to this company at September 30, 2019. Amounts payable to this company were minimal at December 31, 2018.

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 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, 2018, as filed with the SEC on March 5, 2019.

Overview

We are a medical technology company that has developed and is commercializing an innovative and minimally invasive implantable neurostimulation system for sacral neuromodulation ("SNM") therapy. SNM therapy is primarily used to treat patients with urinary urgency incontinence ("UUI") and urinary urgency frequency ("UUF"), which are together referred to as overactive bladder ("OAB"), as well as 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 and only rechargeable SNM system that is designed to last approximately 15 years and is 60% smaller than existing technology. We believe our r-SNM System has the potential to disrupt and grow the estimated $650 million global SNM market in 2018, which is currently controlled by a single participant.

Since we commenced operations in late 2013, our activities have consisted primarily of developing our r-SNM System, conducting our RELAX-OAB post-market clinical follow up study in Europe and our ARTISAN-SNM pivotal clinical study in the United States and Europe, filing for regulatory approvals and hiring and training our U.S. commercial team in advance of the commercial launch of the r-SNM System in the United States. We have marketing approvals in Europe, Canada, and Australia for OAB, UR, and FI and have initiated limited commercial efforts in Europe and Canada in late 2018. To date, we have derived modest revenue from international operations in select markets including England, the Netherlands and Canada. 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. Accordingly, we began U.S. commercialization of our system in the fourth quarter of 2019.

Our ability to generate revenue and become profitable will depend on our ability to successfully commercialize our r-SNM System and any product enhancements we may advance in the future. Although we have had limited commercial activities in Europe and Canada, our main priority is the United States, where 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 sales and marketing organization by hiring dedicated sales and clinical personnel to market and support our product in the United States and Canada. Specifically, we hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. In addition, we plan to strategically expand into certain international markets. If we are unable to accomplish any of these objectives, it could have a significant negative impact on our future revenue. If we fail to generate revenue in the future, our business, results of operations, financial condition, cash flows, and future prospects would be materially and adversely affected.

We also intend to continue to make investments in research and development efforts to develop improvements and enhancements to our r-SNM System. We expect to derive future revenue by increasing patient and physician awareness of 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 the EU, such as Germany, France, and the United Kingdom. Annual healthcare budgets generally determine the number of SNM systems that will be paid for by the payor in these single-payor system countries and regions.

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

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 begin to commercialize and market our r-SNM System in the United States.

We incurred net losses of $57.2 million for the nine months ended September 30, 2019, and had an accumulated deficit of $156.8 million as of September 30, 2019. As of September 30, 2019, we had available cash, cash equivalents and short-term investments of approximately $101.5 million, current liabilities of approximately $15.5 million, and long-term liabilities of approximately $18.3 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"). We have invested heavily in product development and continuous improvement to our r-SNM System. We have also made significant investments in clinical studies to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions. Because of these and other factors, we expect to continue to incur net losses for the next few years and we may require additional funding, which may include future equity and debt financings. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material and adverse effect on our business, financial condition, and results of operations.

Initial Public Offering

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

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 granted us a royalty-bearing, sublicensable license to certain patents and know-how (the "AMF IP"), relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (altogether, the "AMF Licensed Products"). The license to the AMF IP allows Axonics to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of:

(i) bladder and bowel dysfunction in humans through the application of electrical energy anywhere in or on the human body;

(ii) chronic pain in humans through the application of electrical energy to the nervous system; and

(iii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve,

excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system.

Generally, the license is non-transferable without the prior written consent of AMF, except to an affiliate of our company or in connection with the acquisition of our company (whether by merger, consolidation, sale or otherwise) or the part of our business to which the License Agreement relates, provided that the assignee agrees in writing to be bound to the terms of the License Agreement to which we are bound.

We granted to AMF a royalty-free, worldwide, sublicensable, perpetual, exclusive license to any patent rights controlled by us that arise out of our improvements to the inventions claimed in the AMF IP (the "Axonics Licensed

IP"). This license granted by us to AMF explicitly excludes uses of the Axonics Licensed IP that are within the scope of the exclusive license of the AMF IP granted by AMF to us. Such license is irrevocable unless we terminate the License Agreement and AMF does not agree to pay us compensation for such license mutually agreed between us and AMF or determined by arbitration in accordance with the terms of the License Agreement. To date, we have not made any improvements to the inventions claimed in the AMF IP that constitute Axonics Licensed IP.

Under the License Agreement, for each calendar year since 2018, we have been obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product Basis equal to the greater of (i) 4% of all net revenue derived from the AMF Licensed Products, and (ii) 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, 2019, we have recorded related royalties of $0.2 million. We have 60 days to pay AMF the royalty amount due under the License Agreement, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

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

Components of Our Results of Operations

Net Revenue

Since we commenced operations in late 2013, our activities have consisted primarily of developing our r-SNM System, conducting our RELAX-OAB post-market clinical follow up study in Europe and our ARTISAN-SNM pivotal clinical study in the United States and Europe, filing for regulatory approvals and hiring and training our U.S. commercial team in advance of the commercial launch of the r-SNM System in the United States. We have marketing approvals in Europe, Canada, and Australia for OAB, UR, and FI and have initiated limited commercial efforts in Europe and Canada in late 2018. To date, we have derived modest revenue from international operations in select markets including England, the Netherlands and Canada. On September 6, 2019, our PMA application for our r-SNM System for the treatment of FI was approved by the 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. Accordingly, we began U.S. commercialization of our system in the fourth quarter of 2019. Our ability to generate revenue and become profitable will depend on our ability to successfully commercialize our r-SNM System and any product enhancements we may advance in the future. Although we have limited commercial activities in Europe and Canada, our main priority is the United States, where we began to commercialize and market our r-SNM System and generate revenue from product sales in the fourth quarter of 2019. We have established a significant commercial infrastructure to support our product launch in the United States. We expect to derive future revenue by increasing patient and physician awareness of our r-SNM System. In addition, we plan to strategically expand into favorable international markets. If we are unable to accomplish any of these objectives, it could have a significant negative impact on our future revenue. If we fail to generate revenue in the future, our business, results of operations, financial condition, cash flows, and future prospects would be materially and adversely affected.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of acquisition costs of the components of our r-SNM System, third-party contract labor costs, overhead costs, as well as distribution-related expenses such as logistics and shipping costs, net of costs charged to customers. The overhead costs include the cost of material procurement and operations supervision and management personnel. We expect overhead costs as a percentage of revenue to decrease as our sales volume increases. In the future, our cost of goods sold will 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. Revenues have been insignificant to date with prices based on evaluation agreements with one-time discounts offered. We expect future gross margin will be affected by a variety of factors, including manufacturing costs, the average selling price of our r-SNM System, the implementation of cost-reduction strategies, inventory obsolescence costs, which may occur when new generations of our r-SNM System are introduced, and to a lesser extent, the sales mix between the United States, Canada, Europe and Australia as our average selling price in the United States is expected to be higher than in Canada, Europe and Australia. Our gross margin may increase over the long term to the extent our production volumes increase and we receive discounts on the costs charged by our contract manufacturers, thereby reducing our per unit costs. Additionally, our gross margin may fluctuate from quarter to quarter due to seasonality.

Research and Development Expenses

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, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Personnel related	$ 3,175	$ 2,088	$ 8,432	$ 5,872
Clinical development	213	981	1,108	3,862
Contract fabrication and manufacturing	244	323	1,469	2,717
Contract R&D and consulting	829	271	1,939	1,385
Other R&D expenses	394	235	1,000	783
Total R&D expenses	$ 4,855	$ 3,898	$ 13,948	$ 14,619

General and Administrative Expenses

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

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of 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. Specifically, we hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States. However, we expect 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, and loss on disposal of property and equipment. 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, 2019 and 2018 (in thousands, except percentages):

	Three Months Ended September 30,		Period to Period Change	Nine Months Ended September 30,		Period to Period Change
	2019	2018		2019	2018	
Net revenue	$ 1,309	$ 201	$ 1,108	$ 3,874	$ 213	$ 3,661
Cost of goods sold	632	106	526	1,952	111	1,841
Gross profit	677	95	582	1,922	102	1,820
Gross Margin	*51.7%*	*47.5%*		*49.6%*	*48.0%*	
Operating Expenses						
Research and development	4,855	3,898	957	13,948	14,619	(671)
General and administrative	5,162	2,790	2,372	13,539	5,861	7,678
Sales and marketing	15,707	949	14,758	32,371	2,308	30,063
Total operating expenses	25,724	7,637	18,087	59,858	22,788	37,070
Loss from operations	(25,047)	(7,542)	(17,505)	(57,936)	(22,686)	(35,250)
Other Income (Expense)						
Interest income	627	172	455	2,500	448	2,052
Interest and other expense	(586)	(196)	(390)	(1,747)	(579)	(1,168)
Other income (expense), net	41	(24)	65	753	(131)	884
Loss before income tax expense	(25,006)	(7,566)	(17,440)	(57,183)	(22,817)	(34,366)
Income tax expense	—	—	—	1	1	—
Net loss	(25,006)	(7,566)	(17,440)	(57,184)	(22,818)	(34,366)
Foreign currency translation adjustment	(112)	(1)	(111)	(165)	(4)	(161)
Comprehensive loss	$ (25,118)	$ (7,567)	$ (17,551)	$ (57,349)	$ (22,822)	$ (34,527)

Comparison of the Three Months Ended September 30, 2019 and 2018

Net Revenue

Net revenue was $1.3 million for the three months ended September 30, 2019 and was derived from the sale of our r-SNM Systems to customers in Europe and Canada. Net revenue was $0.2 million for the three months ended September 30, 2018 and was derived from the sale of our r-SNM System to customers in Europe and Canada.

Cost of Goods Sold and Gross Margin

We incurred $0.6 million of cost of goods sold for the three months ended September 30, 2019. We incurred $0.1 million of cost of goods sold for the three months ended September 30, 2018. Gross margin was 51.7% for the three months ended September 30, 2019, compared to 47.5% for the three months ended September 30, 2018. The increase in gross margin is primarily due to country and product mix.

Research and Development Expenses

Research and development expenses increased $1.0 million, or 24.5%, to $4.9 million in the three months ended September 30, 2019, compared to $3.9 million in the three months ended September 30, 2018. The increase in research and development expenses was primarily attributable to an increase of $1.1 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, an increase of $0.6 million in contract research and development and consulting expenses, 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 $2.4 million, or 85.0%, to $5.2 million in the three months ended September 30, 2019, compared to $2.8 million in the three months ended September 30, 2018, primarily as a result of an increase of $1.8 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, an increase of $0.2 million in legal and consulting costs, and an increase of $0.2 million in rent expense.

Sales and Marketing Expenses

Sales and marketing expenses increased $14.8 million, or 1,556.1%, to $15.7 million in the three months ended September 30, 2019, compared to $0.9 million in the three months ended September 30, 2018. The increase in sales and marketing expenses was primarily due to an increase of $11.7 million related to personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, as we continued to increase headcount by hiring and training our U.S. commercial team in advance of the commercial launch of our r-SNM System in the United States, an increase of $1.4 million in travel expenses, and an increase of $1.1 million related to expenses for general marketing expenses, conferences and tradeshows.

Other Income (Expense), Net

Other income, net was minimal in the three months ended September 30, 2019. Other expense, net was minimal in the three months ended September 30, 2018.

Income Tax Expense

We incurred no income tax expense during the three months ended September 30, 2019 and 2018.

Comparison of the Nine Months Ended September 30, 2019 and 2018

Net Revenue

Net revenue was $3.9 million for the nine months ended September 30, 2019 and was derived from the sale of our r-SNM Systems to customers in Europe and Canada. Net revenue was $0.2 million for the nine months ended September 30, 2018 and was derived from the sale of our r-SNM System to customers in Europe and Canada.

Cost of Goods Sold and Gross Margin

We incurred $2.0 million of cost of goods sold for the nine months ended September 30, 2019. We incurred $0.1 million of cost of goods sold for the nine months ended September 30, 2018. Gross margin was 49.6% in the nine months ended September 30, 2019, compared to 48.0% for the nine months ended September 30, 2018. The increase in gross margin is primarily due to country and product mix.

Research and Development Expenses

Research and development expenses decreased $0.7 million, or 4.6%, to $13.9 million in the nine months ended September 30, 2019, compared to $14.6 million in the nine months ended September 30, 2018. The decrease in research and development expenses was primarily attributable to a decrease of $2.8 million in clinical development costs to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions, a decrease of $1.2 million in contract fabrication and manufacturing costs, partially offset by an increase of $2.6 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits.

General and Administrative Expenses

General and administrative expenses increased $7.7 million, or 131.0%, to $13.5 million in the nine months ended September 30, 2019, compared to $5.9 million in the nine months ended September 30, 2018, primarily as a result of an increase of $4.3 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, an increase of $1.9 million in legal and consulting costs, and an increase of $0.6 million in rent expense.

Sales and Marketing Expenses

Sales and marketing expenses increased $30.1 million, or 1,302.5%, to $32.4 million in the nine months ended September 30, 2019, compared to $2.3 million in the nine months ended September 30, 2018. The increase in sales and marketing expenses was primarily due to an increase of $23.4 million related to personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, as we continued to increase headcount by hiring and training our U.S. commercial team in advance of the commercial launch of our r-SNM System in the United States, an increase of $3.5 million in travel expenses, and an increase of $2.0 million related to expenses for general marketing expenses, conferences and tradeshows.

Other Income (Expense), Net

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

Income Tax Expense

Income tax expense was minimal for the nine months ended September 30, 2019 and 2018.

Liquidity and Capital Resources

Since we commenced operations in late 2013, we have devoted substantially all of our resources to research and development activities related to our r-SNM System, including clinical and regulatory initiatives to obtain marketing approvals, and hiring and training our sales organization. Additionally, to date, revenue generated from product sales has had minimal impact on our operations, and we have never been profitable. We have marketing approvals in Europe, Canada, and Australia for OAB, UR, and FI. On September 6, 2019, our PMA application for the r-SNM System for the treatment of FI was approved by the FDA and on November 13, 2019, our PMA application for the r-SNM System for the treatment of OAB and UR was approved by the FDA. Our main commercial priority is the United States, where we began to commercialize and market our r-SNM System and generate revenue from product sales in the fourth quarter of 2019. In addition to the United States, we expect to expend capital resources pursuing commercial operations in Europe, Canada, and Australia, the amount and timing of which will depend on a variety of factors, including the size of the developed market for SNM therapy, burdens to entry in any such country or region, and other factors specific to certain respective countries and regions.

We incurred net losses of $57.2 million and $22.8 million for the nine months ended September 30, 2019 and 2018, respectively, and had an accumulated deficit of $156.8 million as of September 30, 2019 compared to $99.6 million at December 31, 2018. We expect to continue to spend a significant amount of our existing resources on sales and marketing activities as we begin to commercialize and market our r-SNM System in the United States. Specifically, we hired and trained a dedicated direct sales organization, comprised of approximately 100 sales professionals, 11 regional sales managers and 35 clinical specialists, in advance of the commercial launch of our r-SNM System in the United States.

As of September 30, 2019, we had cash, cash equivalents and short-term investments of $101.5 million compared to $157.5 million at December 31, 2018. 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. Since inception and prior to our IPO, we raised an aggregate of $114.2 million in gross proceeds from private placements of our preferred stock. On October 30, 2018, we completed our IPO by issuing 9,200,000 shares of common stock, at an offering price of $15.00 per share, for net proceeds of approximately $126.0 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Prior to the IPO, our primary sources of capital were equity financings and amounts borrowed under the Loan Agreement with Silicon Valley Bank. In February 2018, we received $10.0 million from the first tranche (“Tranche A”) of the Term Loan simultaneously with our entry in the Loan Agreement. In October 2018, we received the full $5.0 million from the second tranche (“Tranche B”) and the full $5.0 million from the third tranche (“Tranche C”). As of September 30, 2019, 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 delay the commercialization and marketing of our r-SNM System.

Cash Flows

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

	Nine Months Ended September 30,	
	2019	**2018**
Net cash provided by (used in)		
Operating activities	$ (55,318)	$ (22,074)
Investing activities	32,945	(11,935)
Financing activities	463	29,763
Effect of exchange rate changes on cash and cash equivalents	(165)	(4)
Net decrease in cash and cash equivalents	$ (22,075)	$ (4,250)

Net cash used in operating activities

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 used in operating activities was $22.1 million for the nine months ended September 30, 2018 and consisted primarily of a net loss of $22.8 million, partially offset by non-cash charges of $1.2 million. Non-cash charges consisted primarily of depreciation and amortization and stock-based compensation.

Net cash provided by (used in) investing activities

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 used in investing activities was $11.9 million for the nine months ended September 30, 2018 and consisted of purchases and sales of short-term investments and property and equipment.

Net cash provided by financing activities

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.

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

Indebtedness

In February 2018, we entered into the Loan Agreement with Silicon Valley Bank, which we and Silicon Valley Bank amended in October 2018, 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 through December 31, 2019. On the first day of the end of the interest only period, we will be required to repay the Term Loan in equal monthly installments of

principal plus interest through maturity. Outstanding principal balances under the Term Loan bear interest at the prime rate plus 1.75%.

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

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

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

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

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

In addition, we issued warrants to Silicon Valley Bank and Life Science Loans II, LLC, its counterparty. Each warrant entitles the holder thereof to purchase 40,000 shares of our common stock at an exercise price of $7.50 per share. Each warrant will expire on February 6, 2028. In May 2019, Life Science Loans II, LLC exercised all of its outstanding warrants at an exercise price of $7.50 per share. In July 2019, Silicon Valley Bank exercised all of its outstanding warrants at an exercise price of $7.50 per share.

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, 2018, as filed with the SEC on March 5, 2019. 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, 2019.

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, 2019.

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

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

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, 2018, as filed with the SEC on March 5, 2019. 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, other than as set forth below.

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

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

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

- interruption of supply resulting from modifications to, or discontinuation of, a supplier’s operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier’s failure to produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;

- inability of suppliers to comply with applicable provisions of the laws and regulations enforced by the FDA and state regulatory authorities;
- inability to ensure the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

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

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

Use of Proceeds

On October 30, 2018, our Registration Statement on Form S-1 (File No. 333-227732) relating to our IPO was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 9,200,000 shares of our common stock, including the subsequent sale of 1,200,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a public offering price of $15.00 per share, for aggregate gross proceeds of $138.0 million. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. LLC acted as joint book-running managers for the offering. Wells Fargo Securities, LLC acted as lead manager and SunTrust Robinson Humphrey, Inc. acted as co-manager for the offering.

On November 2, 2018, we closed the sale of such shares, resulting in aggregate cash proceeds to us of approximately $126.0 million, net of $9.7 million of underwriting discounts and commissions and $2.3 million of offering expenses paid or payable by us. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus dated October 30, 2018 and filed with the SEC on November 1, 2018 pursuant to Rule 424(b) under the Securities Act.

Warrant Exercise

On July 16, 2019, we issued and sold 32,529 shares of our common stock to SVB Financial Group ("SVB") in connection with the exercise by SVB of its right to purchase 40,000 shares of our 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. The issuance and sale of the shares of common stock was exempt from registration under the Securities Act, pursuant to Section 3(a)(9) thereof.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

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

\# 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AXONICS MODULATION TECHNOLOGIES, INC.

Date: November 14, 2019

By: /s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer and Director

(Principal Executive Officer)

Date: November 14, 2019

By: /s/ Dan L. Dearen

Dan L. Dearen

President and Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 31.1

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) [Omitted pursuant to Exchange Act Rules 13a-14(a) and 15d-15(a)];

   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 14, 2019

By: /s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer and Director

(Principal Executive Officer)

Exhibit 31.2

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) [Omitted pursuant to Exchange Act Rules 13a-14(a) and 15d-15(a)];

   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 14, 2019

By: /s/ Dan L. Dearen

Dan L. Dearen

President and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Axonics Modulation Technologies, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2019 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 14, 2019

By: /s/ Raymond W. Cohen

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

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

Exhibit 32.2

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

In connection with the Quarterly Report of Axonics Modulation Technologies, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2019 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 14, 2019

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.