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, 2018

or

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

For the transition period from _____ to _____

Commission File Number: 001-38721

Axonics Modulation Technologies, Inc.

(Exact name of registrant as specified in its charter)

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

(949) 396-6322

(Registrant's telephone number, including area code)

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

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

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

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

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

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

As of December 11, 2018, 27,805,103 shares of the registrant's common stock, par value $0.0001 per share, were outstanding.

TABLE OF CONTENTS

		Page
	Special Note Regarding Forward-Looking Statements	
	PART I—FINANCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements (unaudited)	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Comprehensive Loss	2
	Condensed Consolidated Statements of Mezzanine Equity	3
	Condensed Consolidated Statements of Stockholders' Deficit	4
	Condensed Consolidated Statements of Cash Flows	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	35
Item 4.	Controls and Procedures	35
	PART II—OTHER INFORMATION	
Item 1.	Legal Proceedings	37
Item 1A.	Risk Factors	37
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	37
Item 3.	Defaults Upon Senior Securities	37
Item 4.	Mine Safety Disclosures	37
Item 5.	Other Information	37
Item 6.	Exhibits	38
	Signatures	40

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, 2018	December 31, 2017
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 20,148	$ 24,398
Short-term investments	11,069	—
Accounts receivable	219	—
Inventory	2,148	1,541
Prepaid expenses and other current assets	1,751	980
Total current assets	35,335	26,919
Property and equipment, net	2,817	1,530
Intangible asset, net	455	541
Other assets	3,712	422
Total assets	$ 42,319	$ 29,412
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 1,983	$ 1,616
Accrued liabilities	2,713	789
Lease liability, current portion	800	—
Total current liabilities	5,496	2,405
Lease liability, net of current portion	3,453	135
Debt, net of unamortized debt issuance costs	9,056	—
Total liabilities	18,005	2,540
Mezzanine Equity		
Convertible Preferred Stock		
Series A Convertible Preferred Stock, par value $0.0001, 1,030,000 shares authorized, 719,500 shares issued and outstanding at September 30, 2018 and December 31, 2017; aggregate liquidation preference of $15,829 at September 30, 2018 and December 31, 2017	14,021	14,021
Series B-1 Convertible Preferred Stock, par value $0.0001, 2,529,862 shares authorized, 1,925,302 shares issued and outstanding at September 30, 2018 and December 31, 2017; aggregate liquidation preference of $15,248 at September 30, 2018 and December 31, 2017	13,757	13,757
Series B-2 Convertible Preferred Stock, par value $0.0001, 2,537,231 shares authorized, 2,213,794 shares issued and outstanding at September 30, 2018 and December 31, 2017; aggregate liquidation preference of $19,481 at September 30, 2018 and December 31, 2017	17,572	17,572
Series C Convertible Preferred Stock, par value $0.0001, 6,188,888 and 3,888,889 shares authorized at September 30, 2018 and December 31, 2017, respectively; 4,131,546 and 1,898,213 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively; aggregate liquidation preference of $37,184 and $17,084 at September 30, 2018 and December 31, 2017, respectively	36,776	16,877
Noncontrolling interest in Axonics Europe, S.A.S.	31,066	31,066
Stockholders' Deficit		
Common Stock, par value $0.0001, 17,500,000 and 15,000,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 2,830,591 and 2,776,583 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	3,336	2,900
Stock subscriptions receivable	(1,824)	(1,753)
Accumulated deficit	(89,984)	(67,166)
Accumulated other comprehensive loss	(406)	(402)
Total stockholders' deficit	(88,878)	(66,421)
Total liabilities, mezzanine equity and stockholders' deficit	$ 42,319	$ 29,412

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,	
	2018	2017	2018	2017
Net revenue	$ 201	$ 128	$ 213	$ 128
Cost of goods sold	106	118	111	118
Gross profit	95	10	102	10
Operating Expenses				
Research and development	3,898	3,132	14,619	8,959
General and administrative	2,790	1,103	5,861	3,520
Sales and marketing	949	368	2,308	767
Total operating expenses	7,637	4,603	22,788	13,246
Loss from operations	(7,542)	(4,593)	(22,686)	(13,236)
Other Income (Expense)				
Interest income	172	79	448	121
Other expense	(196)	(8)	(579)	(13)
Other income (expense), net	(24)	71	(131)	108
Loss before income tax expense	(7,566)	(4,522)	(22,817)	(13,128)
Income tax expense	—	—	1	1
Net loss	(7,566)	(4,522)	(22,818)	(13,129)
Foreign currency translation adjustment	(1)	519	(4)	588
Comprehensive loss	$ (7,567)	$ (4,003)	$ (22,822)	$ (12,541)
Net loss per share, basic and diluted (see Note 1)	$ (2.67)	$ (1.67)	$ (8.10)	$ (5.26)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	2,830,591	2,705,138	2,817,652	2,494,424

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Series A Preferred Stock		Series B-1 Preferred Stock		Series B-2 Preferred Stock		Series C Preferred Stock		Noncontrolling	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Interests	Total
Balance at December 31, 2017	719,500	$ 14,021	1,925,302	$ 13,757	2,213,794	$ 17,572	1,898,213	$ 16,877	$ 31,066	$ 93,293
Issuance of Series C Preferred Stock at $9.00 per share for cash, net of issuance costs of $199 (unaudited)	—	—	—	—	—	—	2,233,333	19,899	—	19,899
Balance at September 30, 2018 (unaudited)	719,500	$ 14,021	1,925,302	$ 13,757	2,213,794	$ 17,572	4,131,546	$ 36,776	$ 31,066	$ 113,192

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock		Additional Paid-in	Stock Subscriptions	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Receivable	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 (unaudited)	48,720	—	71	(71)	—	—	—
Issuance of Common Stock for employee stock option exercises for cash (unaudited)	5,288	—	6	—	—	—	6
Stock-based compensation (unaudited)	—	—	359	—	—	—	359
Foreign currency translation adjustment (unaudited)	—	—	—	—	—	(4)	(4)
Net loss (unaudited)	—	—	—	—	(22,818)	—	(22,818)
Balance at September 30, 2018 (unaudited)	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,	
	2018	**2017**
Cash Flows from Operating Activities		
Net loss	$ (22,818)	$ (13,129)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	663	514
Stock-based compensation	359	370
Other items	146	—
Changes in operating assets and liabilities		
Accounts receivable	(219)	(64)
Inventory	(607)	(813)
Prepaid expenses and other current assets	(911)	(249)
Other assets	(120)	(45)
Accounts payable	367	498
Accrued liabilities	1,143	137
Lease liability	(77)	(66)
Net cash used in operating activities	(22,074)	(12,847)
Cash Flows from Investing Activities		
Purchases of property and equipment	(1,006)	(492)
Purchases of short-term investments	(23,029)	—
Proceeds from sale of short-term investments	12,100	—
Net cash used in investing activities	(11,935)	(492)
Cash Flows from Financing Activities		
Payment of debt issuance costs	(142)	—
Proceeds from debt	10,000	—
Proceeds from exercise of stock options	6	22
Proceeds from issuance of Preferred Stock and noncontrolling interest	20,098	35,000
Payment of Preferred Stock issuance costs	(199)	(207)
Net cash provided by financing activities	29,763	34,815
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(4)	588
Net increase (decrease) in cash and cash equivalents	(4,250)	22,064
Cash and cash equivalents, beginning of year	24,398	8,209
Cash and cash equivalents, end of period	$ 20,148	$ 30,273
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ 393	$ —
Cash paid for taxes	$ 1	$ 1
Noncash Investing and Financing Activities		
Common Stock issuance on stock option exercises for promissory notes	$ 71	$ 574
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 focused on the design, development, and commercialization of innovative and minimally invasive sacral neuromodulation solutions. The Company has designed and developed the r-SNM System, which delivers mild electrical pulses to the targeted sacral nerve in order to restore normal communication to and from the brain to reduce the symptoms of overactive bladder ("OAB"), 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. To date, the Company has obtained marketing approvals in Europe, Canada, and Australia for OAB, UR, and FI. The Company has derived minimal revenue from its operations, and its activities have consisted primarily of developing the r-SNM System, conducting its RELAX-OAB post-market clinical follow-up study in Europe, and its ARTISAN-SNM pivotal clinical study in the United States.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company, its wholly-owned subsidiaries, Axonics Modulation Technologies U.K. Limited and Axonics Modulation Technologies Australia Pty Ltd, as well as Axonics Europe, S.A.S., a variable interest entity, in which the Company exercises control and is determined to be the primary beneficiary. The interests held by the other investors in Axonics Europe can be converted at any time into a fixed number of shares of the Company's preferred stock pursuant to the terms of a Fourth Amended and Restated Share Exchange Agreement, dated June 30, 2017 (the "Share Exchange Agreement"). Due to this conversion right, the investors' interests are considered to be protected from any losses in Axonics Europe (see Note 6). Therefore, the Company is considered responsible for absorbing the losses of Axonics Europe and as such, has a variable interest in Axonics Europe. Axonics Europe has no equity at risk and is therefore considered a variable interest entity since it is dependent on the Company to finance its activities. The investors in Axonics Europe have entered into an agreement with the Company acknowledging that their investment is not intended to give them voting control over Axonics Europe and they have agreed to vote as directed by the Company's board of directors. Therefore, the Company is the primary beneficiary of Axonics Europe and consolidates this entity. Axonics Modulation Technologies U.K. Limited and Axonics Europe, S.A.S. did not have significant operations for the years ended December 31 2017 and 2016 or for the nine months ended September 30, 2018 and 2017. Intercompany accounts and transactions have been eliminated in consolidation.

Basis of Presentation

The accompanying condensed consolidated balance sheet as of September 30, 2018, the interim consolidated statements of comprehensive loss for the three and nine months ended September 30, 2018 and 2017, and the consolidated statements of mezzanine equity, stockholders' deficit, and cash flows for the nine months ended September 30, 2018 and 2017, and the related footnote disclosures are unaudited. These unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and, in management's opinion, on a basis consistent with the audited consolidated financial statements and reflect all adjustments, which only include normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2018 and its results of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, and the condensed consolidated statements of mezzanine equity, stockholders' deficit, and cash flows for the nine months ended September 30, 2018 and 2017.

The results for the nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other interim period.

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.

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, 2018 and 2017, relates entirely to the sale of product to four customers. The Company recognizes revenue when title and risk of loss pass to customers, which is typically when the customer takes possession of the product. In May 2014, the 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 ASU 2014-09 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and superseded most of the existing revenue recognition guidance, including industry-specific guidance. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 applies to all contracts with customers except those that are within the scope of other topics in the FASB ASC. Effective January 1, 2018, the Company early adopted the comprehensive new revenue recognition standard using the modified retrospective method. As the Company generated minimal revenue 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.

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 with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based upon quoted market prices at period end (Level 1 inputs in the fair value hierarchy) and consists primarily of commercial paper and U.S. government securities. Unrealized gains or losses, deemed temporary in nature, are reported as a separate component of comprehensive income (loss). There were no unrealized gains or losses during the three and nine months ended 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.

Foreign Currency Translation

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Costs and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' deficit in accumulated other comprehensive loss until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss). As of September 30, 2018 and December 31, 2017, 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, 2018 and December 31, 2017. Foreign currency transaction gains and losses are included in results of operations and have not been significant for the periods presented.

Inventory

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

The Company capitalizes inventory produced for commercial sale. Costs associated with developmental products prior to satisfying the Company's inventory capitalization criteria are charged to research and development expense as incurred.

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

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

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

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

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

The Company began capitalizing the r-SNM System manufacturing costs as inventory following both the receipt of regulatory approval from the European and Canadian regulatory bodies and the Company's intent to commercialize, which occurred in 2017. As of September 30, 2018, the Company had $0.9 million and $1.3 million of finished goods inventory and raw materials inventory, respectively, on hand. As of December 31, 2017, the Company had $0.2 million and $1.3 million of finished goods inventory and raw materials inventory, respectively, on hand. As of September 30, 2018 and December 31, 2017, there were minimal work-in-process inventory on hand.

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

Property and Equipment

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

Intangible Asset

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

Impairment of Long-Lived Assets

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

Leases

Through December 31, 2017, the Company recognized rent expense related to operating leases on a straight-line basis over the terms of the leases and, accordingly, recorded the difference between cash rent payments and recognition of rent expense as a deferred rent liability. Landlord-funded leasehold improvements were also recorded as deferred rent liabilities and were amortized as a reduction of rent expense over the noncancelable term of the related operating lease.

Effective January 1, 2018, the Company early adopted 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. Adoption of the standard required us to restate certain previously reported results, including the recognition of additional ROU assets and lease liabilities for existing operating leases. The Company recorded an ROU asset of approximately $0.1 million on its condensed consolidated balance sheets at September 30, 2018 and December 31, 2017, related to its existing operating lease. The Company also recorded a lease liability of approximately $0.2 million and $0.3 million on its condensed consolidated balance sheets at September 30, 2018 and December 31, 2017, respectively, related to its existing operating lease. The initial adoption of this standard did not have an impact on the Company’s consolidated statements of comprehensive loss. The Company determines if an arrangement is a lease at inception and includes operating leases on the Company’s consolidated balance sheets. The operating lease ROU asset is included within the Company’s other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company’s 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, 2018 and December 31, 2017, the remaining lease terms for all of the Company’s operating leases were6.8 years and 1.8 years, respectively. The discount rate used to determine the present value of all of the Company’s operating leases’ future payments was 6.75% (see Note 4 regarding the Company’s new lease).

Noncontrolling Interests

Noncontrolling interests reflected in mezzanine equity are adjusted to the greater of their fair value or carrying value as of each balance sheet date through a charge to additional paid-in capital, if necessary. If classification and presentation outside of permanent equity is not considered necessary, noncontrolling interests are presented as a component of permanent equity on our consolidated balance sheets. On the Company’s consolidated statements of

comprehensive loss, expenses and net loss from less-than-wholly-owned consolidated subsidiaries are reported at the consolidated amounts, including both the amounts attributable to the Company and noncontrolling interests.

Research and Development

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

Income Taxes

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

Stock-Based Compensation

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

Preferred Stock

As provided for in the Company's Certification of Incorporation, liquidation relates to each of the following:

- acquisition of the Company by another entity through a reorganization, merger or consolidation by with the Company's existing stockholders do not continue to hold more than 50% of the surviving or acquiring entity;
- transactions (or series of transactions) in which stockholders transfer more than 50% of the voting power of the Company;
- sale or disposition of substantially all of the Company's assets; and
- any liquidation, dissolution or winding up of the Company.

Certain of the above items are considered deemed redemption features that are not solely in the control of the Company. As a result, the Company's convertible preferred stock is classified as mezzanine equity on the consolidated balance sheets. However, as each of the deemed liquidation events are not considered probable of occurring, the instruments are not required to be re-measured in the reporting period.

Net Loss per Share of Common Stock

Basic net loss per 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, preferred stock warrants, and common stock options are considered to be potentially dilutive securities. Because the Company has reported a net loss in all periods presented, diluted net loss per 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, 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. For the three and nine months ended September 30, 2017, there were 11,579,432 and 10,282,990

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 May 2014, the FASB issued ASU 2014-09, a comprehensive new revenue recognition standard that will supersede previous existing revenue recognition guidance. The standard is intended to clarify the principles of recognizing revenue and create common revenue recognition guidance between GAAP and International Financial Reporting Standards. The standard also requires expanded disclosures surrounding revenue recognition. During fiscal year 2016, the FASB issued additional clarification guidance on the new revenue recognition standard which also included certain scope improvements and practical expedients. The Company early adopted this guidance effective January 1, 2018 using the modified retrospective method. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements or related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)", a comprehensive new lease standard that will supersede previous lease guidance. The standard requires a lessee to recognize assets and liabilities related to long-term leases that were classified as operating leases under previous guidance in its balance sheet. An asset would be recognized related to the right to use the underlying asset and a liability would be recognized related to the obligation to make lease payments over the term of the lease. The standard also requires expanded disclosures surrounding leases. The Company adopted this guidance effective January 1, 2018. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases. Adoption of the standard required the Company to restate certain previously reported results, including the recognition of additional ROU assets and lease liabilities for operating leases. The Company recorded an ROU asset of approximately $0.1 million on its condensed consolidated balance sheets at September 30, 2018 and December 31, 2017, respectively. The Company also recorded a lease liability of approximately $0.2 million and $0.3 million on its condensed consolidated balance sheets at September 30, 2018 and December 31, 2017, respectively. The adoption of this standard did not have an impact on the Company's consolidated income statements.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting", which simplifies authoritative guidance to simplify the accounting for certain aspects of share-based compensation. This guidance addresses the accounting for income tax effects at award settlement, the use of an expected forfeiture rate to estimate award cancellations prior to the vesting date and the presentation of excess tax benefits and shares surrendered for tax withholdings on the statement of cash flows. The Company adopted this guidance effective January 1, 2018. This guidance requires all income tax effects of awards (resulting from an increase or decrease in the fair value of an award from grant date to the vesting date) to be recognized in the income statement when the awards vest or are settled which is a change from previous guidance that required such activity to be recorded in paid-in capital within stockholders' equity. Under this guidance, excess tax benefits are also excluded from the assumed proceeds available to repurchase shares in the computation of diluted earnings (loss) per share. This guidance also eliminates the requirement to estimate forfeitures, but rather provides for an election that would allow entities to account for forfeitures as they occur. The Company made an entity-wide accounting policy election to continue to estimate the number of awards that are expected to vest. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements or related disclosures.

In October 2016, the FASB issued ASU No. 2016-16, "Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory", which amends the accounting for income taxes on intra-entity transfers of assets other than inventory. This guidance requires that entities recognize the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The income tax consequences on intra-entity transfers of inventory will continue to be deferred until the inventory has been sold to a third party. This guidance is effective for fiscal years beginning after December 15, 2017, which was the Company's first quarter of fiscal year 2018, and requires a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. Early adoption is permitted at the beginning of a fiscal year. The adoption of this guidance did not have a material impact on the consolidated financial statements or related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting", which provides clarification on accounting for modifications in share-based payment

awards. This guidance is effective for fiscal years beginning after December 15, 2017, which was the Company's first quarter of fiscal year 2018, with early adoption permitted. The adoption of this guidance did not have an impact on the Company's consolidated financial statements or related disclosures.

In June 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, with early adoption permitted. The guidance should be applied to new awards granted after the date of adoption. The adoption of this guidance is not expected to have an impact on the Company's consolidated financial statements or related disclosures unless there are modifications to the Company's share-based payment awards.

Note 2. Property and Equipment

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

	September 30, 2018	December 31, 2017
Research and development equipment	$ 878	$ 783
Computer hardware and software	725	545
Tools and molds	1,076	877
Leasehold improvements	1,480	297
Furniture and fixtures	387	181
	4,546	2,683
Less: accumulated depreciation and amortization	(1,729)	(1,153)
	$ 2,817	$ 1,530

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. Depreciation and amortization expense of property and equipment was $0.2 million and $0.4 million for the three and nine months ended September 30, 2017, respectively.

Note 3. Intangible Asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The intangible asset was recorded at its fair value of $1.0 million at the date contributed in 2013, which is the gross carrying amount of the intangible asset at September 30, 2018 and December 31, 2017. Accumulated amortization of the intangible asset is $0.5 million at September 30, 2018 and December 31, 2017. The Company recorded expense for the amortization of intangible assets of $0.1 million during the nine months ended September 30, 2018, and 2017. The amortization of intangible assets were minimal during the three months ended September 30, 2018 and 2017. The estimated future amortization expense as of September 30, 2018, is as follows (in thousands):

2018	$	29
2019		115
2020		115
2021		115
2022		81
	$	455

Note 4. Commitments

Operating Leases

In August 2014, the Company entered into a five-year operating lease for approximately 12,215 square feet of office space beginning on November 1, 2014, and expiring on October 31, 2019. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term.

In November 2017, the Company entered into a new lease agreement (the "Lease") with its current landlord, The Irvine Company, LLC, for the lease of approximately 25,548 square feet of office space of a building located in Irvine, California. The Company is using the premises as its new principal executive offices and for general office, research and development, lab, and manufacturing uses. The Company is utilizing its old currently-leased space through the lease expiration date to conduct the training of its sales team.

Unless earlier terminated, the term of the Lease (the "Initial Term") will expire on the final day of the calendar month following the seventh anniversary of the commencement date. The commencement date was set as August 2018. The Company did not control the leased premises before the commencement date. The aggregate base rent due over the Initial Term under the terms of the Lease is approximately $5.3 million (without giving effect to certain rent abatement terms). The Company is also responsible for the payment of additional rent to cover certain costs, taxes, and insurance. Based on the estimated monthly additional rent for 2018 as set forth in the Lease, the Company estimates that the additional rent during the Initial Term will be approximately $3.8 million. The Company also paid approximately $1.2 million for leasehold improvements, net of the tenant improvement allowance provided in the Lease of approximately $0.8 million.

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

At the commencement date of the Lease, the Company recorded an ROU asset of approximately $3.3 million and a lease liability of approximately $4.2 million on its condensed consolidated balance sheet, calculated using the Initial Term of seven years. Total lease incentives excluded from the calculation of the ROU asset were approximately $0.9 million. 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. As of September 30, 2018 and December 31, 2017, the remaining lease term for all of the Company's operating leases

were 6.8 years and 1.8 years, respectively. The discount rate used to determine the present value of all of the Company's operating leases' future payments was 6.75%.

Rent expense (including the Company's proportionate share of taxes, insurance, and maintenance expenses) for the three and nine months ended September 30, 2018 was $0.2 million and $0.4 million, respectively. Rent expense (including the Company's proportionate share of taxes, insurance, and maintenance expenses) for the three and nine months ended September 30, 2017 was $0.1 million and $0.2 million, respectively.

The future minimum lease payments of this operating lease as of September 30, 2018, are as follows (in thousands):

2018	$	219
2019		855
2020		703
2021		735
2022		768
Thereafter		2,146
	$	5,426

License Agreement

In October 2013, the Company entered into the License Agreement with AMF, pursuant to which AMF agreed to license to the Company certain patents and know-how (collectively, the "AMF IP") relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (collectively, the "AMF Licensed Products"). Pursuant to the License Agreement, AMF granted to the Company a royalty-bearing, sublicensable (by written, executed agreements only, subject to the terms of the License Agreement) license under the AMF IP to make, have made, lease, offer to lease, use, sell, offer for sale, market, promote, advertise, import, research, develop and commercialize the AMF Licensed Products worldwide for the treatment of (i) chronic pain in humans through the application of electrical energy to the nervous system, (ii) inflammatory conditions of the human body through the application of electrical energy to the vagus nerve, a nerve that interfaces with parasympathetic control of the heart, lungs and digestive tract, and (iii) urinary and fecal dysfunction in humans through the application of electrical energy anywhere in or on the human body, excluding, in each case, any product or method that involves the placement of electrodes or the administration of electrical stimulation inside the cranial cavity or to the ocular nervous system or the auditory nervous system. Pursuant to the License Agreement, the Company is obligated to pay a 4% royalty of all net revenue derived from the AMF Licensed Products if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to the Company by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case, subject to certain adjustments. The initial term of the License Agreement is from October 1, 2013 to October 1, 2033, and will automatically continue until all patents are no longer in force. The Company generated net revenue of $0.2 million and $0.2 million during the three and nine months ended September 30, 2018, respectively, and recorded minimal related royalties during the three and nine months ended September 30, 2018. The Company generated net revenue of $0.1 million and $0.1 million during the three and nine months ended September 30, 2017, respectively, and recorded minimal related royalties during the three and nine months ended September 30, 2017. Beginning in 2018, the Company is required to pay a minimum annual royalty under the License Agreement. The minimum amount will be $75,000 for 2018, with an increase in subsequent years of $25,000 (i.e., $100,000 for 2019) up to a maximum of $200,000 per year. The Company recorded minimum royalties of $0.1 million during the nine months ended September 30, 2018. Minimum royalties were minimal during the three months ended September 30, 2018.

Note 5. Long-Term Debt

In February 2018, the Company entered into the Loan and Security Agreement (the "Loan Agreement"), with Silicon Valley Bank, providing for a term loan (the "Term Loan"). Pursuant to the Loan Agreement, the Company may request up to $20.0 million in three tranches of term loans with such drawn obligations maturing on June 1, 2021. We requested $10.0 million from the first tranche ("Tranche A"), simultaneously with the entry into the Loan Agreement, which is currently outstanding. The Company may request (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%.

See Note 11 for a description of the subsequent amendment to the Loan Agreement in October 2018.

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.

The outstanding balance of the Term Loan at September 30, 2018 is $10.0 million, which is presented net of unamortized debt issuance costs of $0.9 million. As the Company has met conditions to draw Tranche C and therefore will not commence making monthly principal payments until January 2020, the outstanding balance of the Term Loan is classified in noncurrent liabilities at September 30, 2018.

Expected future principal payments for the term loan are as follows (in thousands):

2018	$	—
2019		3,814
2020		4,059
2021		2,127
	$	10,000

Note 6. Stockholders' Equity

Preferred Stock

As of September 30, 2018, the Company is authorized to issue 12,285,981 shares of convertible preferred stock with a par value of$0.0001 per share. The authorized shares of preferred stock are designated as Series A, Series B-1, Series B-2, and Series C preferred stock in the amount of 1,030,000, 2,529,862, 2,537,231, and 6,188,888 shares, respectively. The rights, preferences, and privileges of the Series A, Series B-1, Series B-2, and Series C preferred stock (collectively, the "Preferred Stock") are as follows:

Dividends

The holders of the outstanding shares of Preferred Stock are entitled to receive, when and if declared by the board of directors, a noncumulative dividend prior and in preference to any declaration or payment of any dividend of the common stock of the Company. As of September 30, 2018, no dividends have been declared since inception.

Conversion

Each share of Preferred Stock is convertible at any time, at the option of the holder, into that number of fully paid shares of common stock as determined by dividing the original issue price by the conversion price for the shares. The original issue price was $20.00, $7.20, $8.00, and $9.00 per share for Series A, B-1, B-2, and C, respectively. The conversion price is subject to adjustment in accordance with the provisions contained in the Company's Certificate of Incorporation. As of September 30, 2018 the conversion price for Series A, B-1, B-2, and C was $8.63, $6.00, $6.67, and $7.50 per share, respectively, based on the retroactive adjustment due to the Company's 1.2-for-1 forward stock split described in Note 1. As ofDecember 31, 2017, the conversion price for Series A, B-1, B-2, and C was $8.83, $6.00, $6.67, and $7.50 per share, respectively, based on the retroactive adjustment due to the Company's 1.2-for-1 forward stock split described in Note 1.

Each share of Preferred Stock automatically converts into shares of common stock at the then effective conversion price for such share immediately upon the earlier of (i) the Company's sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, in which the public offering price per share is not less than $12.00 (as adjusted for recapitalizations and the like) and the aggregate gross proceeds to the Company are not less than $50.0 million or (ii) upon the election of the holders of at least two-thirds of the outstanding shares of Preferred Stock, voting together as a single class on an as-if converted to common stock basis. Each of the events described in (i) and (ii) is referred to as an "Automatic Conversion Event." See Note 11 regarding the Company's initial public offering ("IPO") and related automatic conversion of the Preferred Stock into shares of the Company's common stock.

Liquidation

In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, the holders of Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of the common stock of the Company by reason of their ownership of such stock, an amount per share for each Preferred Stock share held by them equal to the sum of (i) 1.1 times the original issue price for the Preferred Stock for Series A and Series B holders and 1.0 times the original issue price for the Preferred Stock for Series C holders and (ii) all declared but unpaid dividends (if any) on such share. If upon the liquidation, dissolution, or winding up of the Company, the assets of the Company legally available for distribution to the holders of the preferred stock are insufficient to permit the payment to such holders of the full amounts, then the entire assets of the Company legally available for distribution shall be distributed ratably among the holders of Preferred Stock in proportion to the

full amounts they would otherwise be entitled to receive. After the payment or setting aside for payment to the holders of Preferred Stock of the full amounts specified above, the entire remaining assets of the Company legally available for distribution shall be distributed with equal priority and pro rata among the holders of Preferred Stock and common stock then outstanding in proportion to the number of shares of common stock held by each, with each share of Preferred Stock being treated for this purpose as if it had been converted to common stock at the then-applicable conversion rate.

Voting

The holder of each share of Preferred Stock is entitled to the number of votes equal to the number of shares of common stock into which each share of Preferred Stock can be converted.

Stock Option Plan

In 2014, the Company established its 2014 Stock Option Plan (the "2014 Plan"), which provides for the granting of stock options to employees, directors, and consultants of the Company. Options granted under the 2014 Plan may be either incentive stock options ("ISOs") or nonstatutory stock options ("NSOs"), as determined by the administrator at the time of grant. The term of each option shall be stated in the option agreement; however, the term shall be no more than ten years from the date of the grant thereof. In the case of an ISO granted to an optionee who, at the time the option is granted, owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company, the term of the option shall befive years from the date of grant or such shorter term as may be provided in the option agreement. As of September 30, 2018 and December 31, 2017, a total of 3,178,593 and 2,652,903 shares have been reserved for issuance under the 2014 Plan, respectively. As of September 30, 2018 and December 31, 2017, there were 40,019 and 82,463 shares available for grant under the 2014 Plan, respectively.

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

	September 30, 2018	December 31, 2017
Convertible preferred stock outstanding and issuable	15,813,297	13,079,920
Options outstanding under the 2014 Plan	1,417,979	903,857
Options remaining under the 2014 Plan for future issuance	40,019	82,463
	17,271,295	14,066,240

Preferred Stock outstanding and issuable includes shares of the Company and shares in Axonics Europe, S.A.S., which are exchangeable for the applicable series of Preferred Stock pursuant to the Share Exchange Agreement.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
General and administrative	$ 55	$ 106	$ 211	$ 227
Research and development	44	68	141	143
Sales and marketing	2	—	7	—
	$ 101	$ 174	$ 359	$ 370

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected term (in years)	5.00 - 6.96	5.54 - 6.10	5.00 - 6.96	5.00 - 6.50
Stock volatility	76.01% - 77.03%	75.83% - 76.01%	76.01% - 77.03%	70.61% - 76.01%
Risk-free interest rate	2.26% - 2.81%	1.83% - 2.05%	2.26% - 2.81%	1.82% - 2.05%
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 any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments, whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The assumptions regarding the expected term of the options and the expected volatility of the stock price are subjective, and these assumptions have a significant effect on the estimated fair value amounts. The weighted-average grant date fair value of options granted was $1.32 and $1.32 for the three and nine months ended September 30, 2018, respectively. The weighted-average grant date fair value of options granted was $1.10 and $1.06 for the three and nine months September 30, 2017, respectively.

As of September 30, 2018 and December 31, 2017, there was $1.2 million and $0.9 million, respectively, of total unrecognized compensation cost related to non-vested stock options that is expected to be recognized over a weighted-average period of approximately 2.7 years.

The following table summarizes stock option activity under the 2014 Plan:

	Number of Options	Weighted-Average Exercised Per Share
Outstanding at December 31, 2016	476,451	$ 0.98
Options granted	896,828	1.36
Options exercised	(446,971)	1.33
Options forfeited	(22,451)	0.97
Outstanding at December 31, 2017	903,857	1.18
Options granted	570,179	1.62
Options exercised	(54,008)	1.41
Outstanding at September 30, 2018	1,417,979	$ 1.35
Options exercisable at December 31, 2017	638,305	$ 1.18
Options exercisable at September 30, 2018	1,082,080	$ 1.33

The weighted-average remaining contractual term of options outstanding and exercisable is 7.8 years and 8.7 years, respectively, at September 30, 2018 and December 31, 2017. During the three and nine months ended September 30, 2018, stock options covering 5,288 and 54,008 shares of common stock, respectively, with a total intrinsic value of $0 for each of the periods, were exercised. During the three and nine months ended September 30, 2017, stock options covering 282,026 and 446,971 shares of common stock, respectively, with a total intrinsic value of $0 for each of the periods, were exercised.

Stock Subscriptions Receivable

As of September 30, 2018, several members of management of the Company have exercised stock options covering 1,685,597 shares of common stock, in exchange for promissory notes with a principal balance of $1.8 million. These promissory notes bear interest at a rate of 4.5% per annum and are due in full in 2020 to 2022. The promissory notes can become due earlier if the shares of common stock received from the option exercises are sold, the employee terminates employment with the Company, or pursuant to other provisions specified in the notes. The notes are secured by the shares of common stock received from the option exercises. See Note 11 regarding the subsequent forgiveness of all outstanding balances relating to the Stock subscriptions receivable.

Preferred Stock Warrants

In February 2018, in connection with the Company's entry into the Loan Agreement (as defined below), the Company issued warrants to Silicon Valley Bank and Life Science Loans II, LLC, its counterparty. Each warrant entitles the holder thereof to purchase up to 33,333 shares of the Series C Preferred Stock at an exercise price of $9.00 per share. Initially, each warrant is exercisable for 16,667 shares of Series C Preferred Stock. If the Company draws on Tranche B, an additional 8,333 shares will become exercisable under each warrant and if the Company draws on Tranche C, an additional 8,333 shares will become exercisable under each warrant. Each warrant will expire on February 6, 2028. As of September 30, 2018, warrants to purchase 33,333 shares of the Company's Series C Preferred Stock were outstanding and are considered liabilities, the value of which is recorded in current liabilities and will be required to be adjusted to fair value each reporting period with the change reflected in the statements of comprehensive loss, if any. Additional warrants exercisable into a total of 33,332 Series C Preferred Stock shares remain issuable as of September 30, 2018. The fair value of the warrants was estimated at $0.2 million as of September 30, 2018 using the Black-Scholes option pricing model with the following assumptions: expected life of 10 years, risk-free interest rate of 2.74% and stock volatility of 76.01%. See Note 11 regarding the Company's IPO and related impact on the preferred stock warrants.

Note 7. Noncontrolling Interest

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

The Company presents noncontrolling interest as mezzanine equity on the consolidated balance sheets due to the Share Exchange Agreement that provides the holders of the equity in Axonics Europe S.A.S. (excluding the Company) the unilateral right to exchange its equity interest in Axonics Europe S.A.S. for Preferred Stock of the Company at any time. The Company's Preferred Stock is presented as mezzanine equity, and as such, the rights under the Share Exchange Agreement require the noncontrolling interest to be presented as mezzanine equity as well.

Comprehensive loss attributable to the noncontrolling interest in Axonics Europe S.A.S. are absorbed by the Company since the investors are protected from any losses in this entity due to the conversion right. Changes in amounts attributable to the redeemable noncontrolling interest are presented in the Company's consolidated statements of mezzanine equity.

Note 8. Income Taxes

The Company used an annual effective tax rate approach to calculate income taxes for the three and nine months ended September 30, 2018 and 2017. The annual effective tax rate of approximately 0% differs from the federal statutory tax rate due primarily to providing a full valuation allowance on deferred tax assets.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law in the United States. Among other items, the Tax Act reduces the federal corporate tax rate to 21% from the existing maximum rate of 35%, effective January 1, 2018. As a result, the Company revalued its net deferred tax asset at the new lower tax rate at December 31, 2017. At December 31, 2017, the Company had federal and California net operating loss ("NOL") carryforwards of approximately $65.2 million. Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), use of the Company's NOL carryforwards may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a rolling three-year period. The Company has not performed an analysis of changes in ownership for purposes of these 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 2033 and 2037. At December 31, 2017, the Company also had research and development tax credit carryforwards of approximately $1.9 million, which will expire in 2035 to 2037. Approximately $0.5 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, 2018 and December 31, 2017, as they are expected to be utilized in 2018 as a credit to offset payroll taxes. The remaining amount of research and development tax credit carryforwards are included in net deferred tax assets.

Note 9. Employee Benefit Plan

The Company sponsors a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pre- or post-tax basis. Contributions to the plan by the Company may be made at the discretion of the board of directors. During the three and nine months ended September 30, 2018, the Company contributions to the plan amounted to $0.1 million and $0.2 million, respectively. During the three and nine months ended September 30, 2017, the Company contributions to the plan amounted to $0.1 million and $0.2 million, respectively.

Note 10. Related Party Transactions

The Company incurred $0.1 million during each of the nine months ended September 30, 2018 and 2017 to a scientific advisor who is also a non-management stockholder of the Company. The Company incurred minimal amounts during each of the three months ended September 30, 2018 and 2017. Amounts payable to this advisor were minimal at September 30, 2018 and December 31, 2017.

The Company incurred $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. The Company incurred $0.2 million during the nine months ended September 30, 2017, for engineering and design services to a company that is owned by a non-management stockholder of the Company. The Company incurred minimal amounts during the three months ended September 30, 2017. There were no amounts payable to this company at September 30, 2018 or December 31, 2017.

The 2014 Plan allows for certain members of management to purchase vested options and unvested options (subject to repurchase rights) through a full recourse promissory note and stock pledge agreement. The promissory notes outstanding are recorded as "Stock subscriptions receivable" in the accompanying condensed consolidated balance sheets. The aggregate principal amounts owed by certain members of management as of September 30, 2018 was $1.8 million. The notes were forgiven on October 4, 2018, refer to Note 11 for discussion of the note forgiveness.

Note 11. Subsequent Events

Forgiveness of Stock Subscription Receivable

On October 4, 2018, the Company entered into agreements with certain officers and directors to terminate each of their respective promissory notes and to forgive all respective obligations for payment thereof in connection with the Company's IPO. As a result, on October 4, 2018, the Company forgave all outstanding stock subscriptions receivable referenced above in the aggregate amount of $1.8 million plus accrued interest, which amount will be recorded as compensation expense.

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.

Term Loan Amendment

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. Warrants to purchase an additional 40,000 shares of the Company's common stock at an exercise price of $7.50 per share became exercisable in conjunction with the additional loan.

Initial Public Offering

On November 2, 2018, the Company completed its 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 estimated 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, resulting in the reclassification of such warrant liability of $0.4 million to additional paid-in-capital.

2018 Omnibus Incentive Plan

On October 18, 2018, the Company adopted the 2018 Omnibus Incentive Plan (the "2018 Plan"), under which the Company may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which it competes. The 2018 Plan provides for awards based on shares of the Company's common stock. Subject to adjustment by the Company's board of directors, the total number of shares authorized to be awarded under the 2018 Plan may not exceed 4,540,019.

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 final prospectus, dated October 30, 2018 and filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) of the Securities Act of 1933, as amended (the "Securities Act").

Overview

We are a medical technology company focused on the design, development, and commercialization of innovative and minimally invasive SNM solutions. SNM therapy is primarily used to treat patients with overactive bladder ("OAB"), fecal incontinence ("FI"), and urinary retention ("UR"). Our proprietary rechargeable sacral neuromodulation ("SNM") system (the "r-SNM System") delivers mild electrical pulses to the targeted sacral nerve in order to restore normal communication to and from the brain to reduce the symptoms of OAB, FI, and UR.

OAB affects an estimated 87 million adults in the U.S. and Europe. Another approximately 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 U.S. 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 r-SNM System offers significant advantages, including being the first and only rechargeable SNM system that is designed to be 60% smaller than existing technology and to last approximately 15 years. We believe our r-SNM System has the potential to disrupt and grow the approximately $605 million global SNM market in 2017, which is currently controlled by a single participant.

We currently have marketing approvals in Europe, Canada, and Australia for OAB, FI, and UR, and on December 3, 2018, submitted a pre-market approval ("PMA") application to the U.S. Food and Drug Administration ("FDA") for OAB and UR indications.

Since we commenced operations in late 2013, we have generated minimal revenue, as our activities have consisted primarily of developing our r-SNM System, conducting our RELAX-OAB post-market clinical follow up study in Europe and our ARTISAN-SNM pivotal study in the United States and Europe, and filing for regulatory approvals.

In the future, if our r-SNM System is approved in the United States, we expect to generate revenue from product sales. Our ability to generate revenue and become profitable will depend on our ability to successfully commercialize our r-SNM System and any product enhancements we may advance in the future. Although we have begun limited commercial activities in Europe, our main priority is the United States, where we expect to begin to commercialize and market our r-SNM System and generate revenue from product sales if and when approved by the FDA. We plan to establish a significant commercial infrastructure in anticipation of potential FDA approval of our r-SNM System and make significant investments to build our sales and marketing organization by hiring dedicated sales personnel, including sales representatives, sales managers and clinical support personnel to market our product in markets throughout United States and Canada. In addition, we plan to strategically expand into certain international markets in Europe.

We also intend to continue to make investments in research and development efforts to develop our next generation r-SNM System and support our future regulatory submissions for expanded labeling. We expect to derive future revenue by increasing patient and physician awareness of our r-SNM System and obtaining additional regulatory approvals.

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.

In addition to our anticipated submission of a PMA based on clinical data from our 129-patient ARTISAN-SNM pivotal clinical study under the investigational device exemption process, we also submitted to the FDA on December 3, 2018 a PMA application, which we refer to as the "literature-based PMA," in which equivalence to an already FDA approved product is claimed based on the review of technical specifications, published clinical studies, and other information. In our filing, we are claiming equivalence to the only FDA approved SNM device, InterStim II.

We anticipate that 90 days after our new submission, we will receive further questions from the FDA as is customary to the PMA submission process. Further, we anticipate using a combination of interactive discussion and written correspondence with the FDA to address any questions that we may receive. Upon our submission of formal responses to these anticipated questions, the FDA will have 90 additional days to reply to our responses.

We will continue to maintain flexibility in our overall PMA pathway. Specifically, the literature-based PMA submission activity does not alter our work on the ARTISAN-SNM pivotal study per protocol, and we believe that the question-response process between us and the FDA in the literature-based PMA will prove beneficial in the overall PMA review process.

We currently outsource the manufacture of all 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.

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.

We incurred net losses of $22.8 million for the nine months ended September 30, 2018, and had an accumulated deficit of $90.0 million as of September 30, 2018. As of September 30, 2018, we had available cash, cash equivalents and short-term investments of approximately $31.2 million, current liabilities of approximately $5.5 million, and long-term liabilities of approximately $12.5 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.

Based on our estimated use of proceeds, together with our existing cash, cash equivalents and short-term investments, we anticipate that the net proceeds from our IPO will be sufficient to fund our projected operating expenses and capital expenditure requirements through the launch and initial commercialization of our r-SNM System. However,

we may require additional funds earlier than we currently expect if, in the event that we are required to conduct additional clinical trials, we experience a delay in receiving marketing approval of our r-SNM System or market acceptance of our r-SNM System is slower than expected.

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

The license is co-exclusive with AMF solely with respect to (i) AMF IP resulting from AMF's performance of any engineering services rendered under the License Agreement, and (ii) AMF's right to use AMF IP for non-commercial research, educational and scholarly purposes.

We granted to AMF a royalty-free, worldwide, sublicensable, perpetual, exclusive license to any patent rights controlled by us that arise out of our improvements to the inventions claimed in the AMF IP (the "Axonics Licensed IP"). This license granted by us to AMF explicitly excludes uses of the Axonics Licensed IP that are within the scope of the exclusive license of the AMF IP granted by AMF to us. Such license is irrevocable unless we terminate the License Agreement and AMF does not agree to pay us compensation for such license mutually agreed between us and AMF or determined by arbitration in accordance with the terms of the License Agreement.

In addition, the License Agreement provides AMF with the option (the "AMF Option") to license from us any intellectual property developed and owned by us or otherwise in our control that is related to electrical stimulation of human tissue, separate from the Axonics Licensed IP and AMF IP, on terms that are materially consistent with the terms upon which we license the AMF IP pursuant to the License Agreement, and subject to field of use restrictions that would be determined upon the exercise of the AMF Option. AMF has expressly declined in writing to exercise the AMF Option.

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

In addition, beginning in 2018, we are required to pay AMF a minimum annual royalty (the "Minimum Royalty"), payable quarterly if the royalty due is in excess of the Minimum Royalty, which will automatically increase each calendar year thereafter, subject to a maximum amount of $200,000 per year. We have accrued $0.1 million as of September 30, 2018 toward AMF Minimum Royalties. Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF the greater of (i) the amount of the 4% royalty referred to above, and (ii) the Minimum Royalty for such calendar year beginning with 2018. We have 60 days to pay AMF this amount, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.

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

As of September 30, 2018, AMF held 888,000 shares of our common stock, 125,000 shares of our Series A preferred stock, and 771,161 shares of our Series B-1 preferred stock. In connection with our IPO, all of our outstanding shares of preferred stock converted into shares of our common stock. John Petrovich, a member of our board of directors, is the President, Chief Executive Officer, Senior Vice President of Business Development, and General Counsel of AMF.

Components of Our Results of Operations

Net Revenue

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

Cost of Goods Sold and Gross Margin

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

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

Research and Development Expenses

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

The following table summarizes our research and development expenses by functional area for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Personnel related	$ 2,088	$ 1,646	$ 5,872	$ 4,517
Clinical development	981	372	3,862	1,031
Contract fabrication and manufacturing	323	404	2,717	1,627
Contract R&D and consulting	271	517	1,385	1,253
Other R&D expenses	235	193	783	531
Total R&D expenses	$ 3,898	$ 3,132	$ 14,619	$ 8,959

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 trade shows, booth exhibition costs, and the related travel for these events. Other sales and marketing expenses include consulting and advisory fees, market access personnel and employee compensation, including stock-based compensation. In anticipation of potential FDA approval, we expect sales and marketing expenses to continue to increase in absolute dollars as we expand our commercial infrastructure to both drive and support our expected growth in revenue. In particular, we plan to hire between 60 and 100 field sales representatives, 10 sales managers and 24 clinical support personnel, all based in the U.S., in anticipation of our potentially receiving FDA approval to support the potential commercial launch in the United States, which will significantly increase our sales and marketing expense. However, we expect sales and marketing expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash equivalents and short-term investments, net of interest expense payable under the Loan Agreement with Silicon Valley Bank, and loss on disposal of property and equipment. Other income (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, 2018 and 2017 (in thousands, except percentages):

	Three Months Ended September 30,		Period to Period Change	Nine Months Ended September 30,		Period to Period Change
	2018	2017		2018	2017	
Net revenue	$ 201	$ 128	$ 73	$ 213	$ 128	$ 85
Cost of goods sold	106	118	(12)	111	118	(7)
Gross profit	95	10	85	102	10	92
Gross Margin	*47.5%*	*7.9%*		*48.0%*	*7.9%*	
Operating Expenses						
Research and development	3,898	3,132	766	14,619	8,959	5,660
General and administrative	2,790	1,103	1,687	5,861	3,520	2,341
Sales and marketing	949	368	581	2,308	767	1,541
Total operating expenses	7,637	4,603	3,034	22,788	13,246	9,542
Loss from operations	(7,542)	(4,593)	(2,949)	(22,686)	(13,236)	(9,450)
Other Income (Expense)						
Interest income	172	79	93	448	121	327
Other expense	(196)	(8)	(188)	(579)	(13)	(566)
Other income (expense), net	(24)	71	(95)	(131)	108	(239)
Loss before income tax expense	(7,566)	(4,522)	(3,044)	(22,817)	(13,128)	(9,689)
Income tax expense	—	—	—	1	1	—
Net loss	$ (7,566)	$ (4,522)	$ (3,044)	$ (22,818)	$ (13,129)	$ (9,689)
Foreign currency translation adjustment	(1)	519	(520)	(4)	588	(592)
Comprehensive loss	$ (7,567)	$ (4,003)	$ (3,564)	$ (22,822)	$ (12,541)	$ (10,281)

Comparison of the Three Months Ended September 30, 2018 and 2017

Net Revenue

Net revenue was $0.2 million for the three months ended September 30, 2018 and was derived from the sale of our r-SNM Systems to customers in Europe and Canada. Net revenue was $0.1 million for the three months ended September 30, 2017 and consisted of a sale to a single customer in Canada.

Cost of Goods Sold and Gross Margin

We incurred $0.1 million of cost of goods sold for the three months ended September 30, 2018 and 2017. Gross margin was47.5% in the three months ended September 30, 2018, compared to 7.9% gross margin in the three months ended September 30, 2017.The increase in gross margin is primarily due to country and product mix, and the lower gross margin in the prior year period is due to a one-time evaluation agreement with a hospital in Canada.

Research and Development Expenses

Research and development expenses increased $0.8 million, or 24.5%, to $3.9 million in the three months ended September 30, 2018 compared to $3.1 million in the three months ended September 30, 2017. The increase in research and development expenses was primarily attributable to an increase of $0.6 million in clinical development costs to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions and an increase of $0.4 million in personnel costs, partially offset by a decrease of $0.3 million in contract fabrication and manufacturing costs and contract research and development and consulting expenses.

General and Administrative Expenses

General and administrative expenses increased $1.7 million, or 189.2%, to $2.8 million in the three months ended September 30, 2018, compared to $1.1 million in the three months ended September 30, 2017, primarily as a result of an increase of $1.2 million in legal and consulting costs and an increase of $0.2 million related to personnel costs.

Sales and Marketing Expenses

Sales and marketing expenses increased $0.6 million, or 157.9%, to $0.9 million in the three months ended September 30, 2018, compared to $0.4 million in the three months ended September 30, 2017. The increase in sales and marketing expenses was primarily due to an increase of $0.3 million related to personnel costs and an increase of $0.3 million related to expenses for conferences and tradeshows.

Other Income (Expense), Net

Other expense, net was minimal for the three 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. Other income, net was $0.1 million in the three months ended September 30, 2017, which was primarily interest income earned on cash equivalents and short-term investments.

Income Tax Expense

Income tax expense was minimal in the three months ended September 30, 2018 and 2017.

Comparison of the Nine Months Ended September 30, 2018 and 2017

Net Revenue

Net revenue was $0.2 million for the nine months ended September 30, 2018 and was derived from the sale of our r-SNM Systems to customers in Europe and Canada. Net revenue was $0.1 million for the nine months ended September 30, 2017 and consisted of a sale to a single customer in Canada.

Cost of Goods Sold and Gross Margin

We incurred $0.1 million of cost of goods sold for the nine months ended September 30, 2018. Gross margin was 48.0% in the nine months ended September 30, 2018, compared to 7.9% gross margin in the nine months ended September 30, 2017.The increase in gross margin is primarily due to country and product mix, and the lower gross margin in the prior year period is due to a one-time evaluation agreement with a hospital in Canada.

Research and Development Expenses

Research and development expenses increased $5.7 million, or 63.2%, to $14.6 million in the nine months ended September 30, 2018 compared to $9.0 million in the nine months ended September 30, 2017. The increase in research and development expenses was primarily attributable to an increase of $2.8 million in clinical development costs to demonstrate the safety and effectiveness of our r-SNM System and to support regulatory submissions, an increase of $1.4 million in personnel costs, an increase of $1.1 million in contract fabrication and manufacturing costs, and an increase of $0.4 million in contract research and development and consulting expenses.

General and Administrative Expenses

General and administrative expenses increased $2.3 million, or 77.9%, to $5.9 million in the nine months ended September 30, 2018, compared to $3.5 million in the nine months ended September 30, 2017, primarily as a result of an increase of $1.3 million in legal and consulting costs and an increase of $0.8 million related to personnel costs.

Sales and Marketing Expenses

Sales and marketing expenses increased $1.5 million, or 200.9%, to $2.3 million in the nine months ended September 30, 2018, compared to $0.8 million in the nine months ended September 30, 2017. The increase in sales and marketing expenses was primarily due to an increase of $0.9 million related to personnel costs and an increase of $0.5 million related to expenses for conferences and tradeshows.

Other Income (Expense), Net

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. Other income, net was $0.1 million in the nine months ended September 30, 2017, which was primarily interest income earned on cash equivalents and short-term investments.

Income Tax Expense

Income tax expense was minimal in the nine months ended September 30, 2018 and 2017.

Liquidity and Capital Resources

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

We incurred net losses of $22.8 million for the nine months ended September 30, 2018, respectively, and had an accumulated deficit of $90.0 million as of September 30, 2018. In anticipation of potential FDA approval, we expect to spend a significant amount of our existing resources on sales and marketing activities as we begin to commercialize and market our r-SNM System in the United States. In particular, we plan to hire between 60 and 100 field sales representatives, 10 sales managers and 24 clinical support personnel, which we will initially endeavor to hire in anticipation of our potentially receiving FDA approval to support the potential commercial launch in the United States, which will significantly increase our sales and marketing expense.

As of September 30, 2018, we had cash, cash equivalents and short-term investments of $31.2 million. Since inception and prior to the 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 to date have been from preferred stock financings and amounts borrowed under the Loan Agreement with Silicon Valley Bank. In February 2018, we received $10.0 million from the first tranche ("Tranche A") of the Term Loan simultaneously with our entry in the Loan Agreement. As of September 30, 2018, we had $10.0 million in outstanding borrowings under the Term Loan and an ability to borrow an aggregate of $10.0 million in the second tranche ("Tranche B") and the third tranche ("Tranche C") of the Term Loan. In October 2018, we requested the full $5.0 million from Tranche B and the full $5.0 million from Tranche C, as discussed below under "Indebtedness." 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 development, commercialization and marketing of our r-SNM System.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	**2017**
Net cash provided by (used in)		
Operating activities	$ (22,074)	$ (12,847)
Investing activities	(11,935)	(492)
Financing activities	29,763	34,815
Effect of exchange rate changes on cash and cash equivalents	(4)	588
Net increase (decrease) in cash and cash equivalents	$ (4,250)	$ 22,064

Net cash used in operating activities

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 used in operating activities was $12.8 million for the nine months ended September 30, 2017 and consisted primarily of a net loss of $13.1 million and a decrease in net operating assets of $0.6 million, partially offset by non-cash charges of $0.9 million. Net operating assets consisted primarily of accounts payable due to timing of payments. Non-cash charges consisted primarily of depreciation and amortization and stock-based compensation.

Net cash used in investing activities

Net cash used in investing activities was $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 used in investing activities was $0.5 million for the nine months ended September 30, 2017 and consisted of purchases of property and equipment.

Net cash provided by financing activities

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.

Net cash provided by financing activities was $34.8 million for the nine months ended September 30, 2017 and consisted primarily of proceeds from the issuance of shares of our Series C preferred stock.

Indebtedness

In February 2018, we entered into the Loan Agreement with Silicon Valley Bank providing for the Term Loan. Pursuant to the Loan Agreement, we may request up to $20.0 million in three tranches of term loans and such drawn obligations mature on June 1, 2021. We requested $10.0 million from Tranche A simultaneously with the entry into the Loan Agreement, which is currently outstanding. We may request (a) Tranche B of an additional $5.0 million after the date commencing on the later of (i) the date that we achieve positive three months results in our ARTISAN-SNM pivotal study, as confirmed to Silicon Valley Bank by a member of our management team and a member of our board of directors, and (ii) July 1, 2018, and ending on December 31, 2018, and (b) Tranche C, for an additional $5.0 million after the date commencing on the later of (i) the date that Silicon Valley Bank receives evidence, in form and substance reasonably satisfactory to Silicon Valley Bank, that we have received our PMA in the United States for our r-SNM System or gross proceeds from the sale of our equity securities of not less than $20.0 million (which condition was satisfied when we issued and sold 2,233,333 shares of our Series C preferred stock in March 2018 for aggregate gross proceeds of $20,099,997), and (ii) January 1, 2019, and ending on March 31, 2019, subject to certain terms and conditions. If either Tranche B or Tranche C is requested, then the maturity of the Term Loan is automatically extended to December 1, 2021.

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

In October 2018, we and Silicon Valley Bank entered into an amendment to the Loan Agreement (the "Loan Amendment"), in connection with which we requested the full $5.0 million from Tranche B and the full $5.0 million from Tranche C. We 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 our receipt of a PMA in the United States for our 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 we do not (i) consummate an initial public offering, with proceeds of no less than $75.0 million, which was consummated in November 2018, (ii) receive PMA approval in the United States for our r-SNM System, or (iii) receive gross proceeds of at least $40.0 million from the sale of our equity securities, in each case on or prior to June 30, 2019. In addition, as a result of our request of the full $5.0 million from Tranche B and the full $5.0 million from Tranche C, the maturity of the Term Loan has been automatically extended to December 1, 2021.

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

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

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

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

While we have not previously breached and are currently in compliance with the covenants contained in the Loan Agreement, we may breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, Silicon Valley Bank may choose to declare an event of default and require that we immediately repay all amounts outstanding under the 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.

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

During the nine months ended September 30, 2018, there have been no material changes outside the ordinary course of business to our contractual obligations disclosed in our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our final prospectus dated October 30, 2018 relating to our Registration Statement on Form S-1 (File No. 333-227732) for our IPO.

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 final prospectus dated October 30, 2018 relating to our Registration Statement on Form S-1 (File No. 333-227732). We have reviewed and determined that those critical accounting policies and estimates remain our critical accounting policies and estimates as of and for the three and nine months ended September 30, 2018.

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.

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

Interest Rate Risk

We had cash, cash equivalents and short-term investments of $31.2 million as of September 30, 2018, which came from private placements of our preferred stock and debt financing arrangements. The goals of our investment policy are liquidity and capital preservation and we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash, cash equivalents and short-term investments. Additionally, the interest rate for borrowings under the Loan Agreement is variable. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Foreign Currency Exchange Rate Risk

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

Inflation Risk

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

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, 2018.

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, 2018 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.

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We currently are not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our results of operations, financial position or cash flows. Regardless of the outcome, any litigation could have an adverse impact on us due to defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

You should carefully consider the information described in the "Risk Factors" section of our final prospectus dated October 30, 2018 relating to our Registration Statement on Form S-1 (File No. 333-227732) for our IPO. There have been no material changes to the risk factors described therein.

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

Unregistered Sales of Equity Securities

None.

Recent Repurchases of Equity Securities

None.

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 of1,200,000 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.

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	Incorporated by Reference				Filed Herewith (X)
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-38721	3.1	11/05/2018	
3.2	Amended and Restated Bylaws.	8-K	001-38721	3.2	11/05/2018	
4.1	Specimen certificate evidencing shares of common stock of the Registrant.	S-1	333-227732	4.1	10/5/2018	
4.2	Fourth Amended and Restated Investors' Rights Agreement, dated March 29, 2018, by and among the Registrant and the Investors party thereto.	S-1	333-227732	4.2	10/5/2018	
4.3	Amendment to Fourth Amended and Restated Investors' Rights Agreement, dated October 17, 2018, by and among the Registrant and the Investors party thereto.	S-1/A	333-227732	4.3	10/22/2018	
4.4	Warrant to Purchase Series C preferred stock, dated February 6, 2018, issued by the Registrant to Silicon Valley Bank.	S-1	333-227732	4.3	10/5/2018	
4.5	Warrant to Purchase Series C preferred stock, dated February 6, 2018, issued by the Registrant to Life Science Loans II, LLC.	S-1	333-227732	4.4	10/5/2018	
10.1+	2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.8	10/22/2018	
10.2+	Form of Option Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.9	10/22/2018	
10.3+	Form of Restricted Shares Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.10	10/22/2018	
10.4+	Form of RSU Award Agreement under 2018 Omnibus Incentive Plan.	S-1/A	333-227732	10.11	10/22/2018	
10.5+#	Form of Debt Forgiveness Agreement and Cancellation of Note (Tax Withholding-Shares).	S-1	333-227732	10.28	10/5/2018	
10.6+#	Form of Debt Forgiveness Agreement and Cancellation of Note (Tax Withholding-Cash).	S-1	333-227732	10.29	10/5/2018	

10.7	Amendment to Loan and Security Agreement, dated October 22, 2018, by and between Silicon Valley Bank and the Registrant.	S-1/A	333-227732	10.31	10/22/2018	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
32.1#	Certifications of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2#	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS**	XBRL Instance Document.					X
101.SCH**	XBRL Taxonomy Extension Schema Document.					X
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.					X

+ Indicates management contract or compensatory plan.

\# The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this 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: December 11, 2018

By: /s/ Raymond W. Cohen

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

Date: December 11, 2018

By: /s/ Danny L. Dearen

Danny 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: December 11, 2018

By: /s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer and Director

(Principal Executive Officer)

Exhibit 31.2

I, Danny 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: December 11, 2018

By: /s/ Danny L. Dearen

Danny 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, 2018 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: December 11, 2018

By: /s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer and Director

(Principal Executive Officer)

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, 2018 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: December 11, 2018

By: /s/ Danny L. Dearen

Danny L. Dearen

President and Chief Financial Officer

(Principal Financial Officer)