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 March 31, 2023

or

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

For the transition period from _____ to _____

Commission File Number: 001-38721

Axonics, Inc.

(Exact name of registrant as specified in its charter)

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

(949) 396-6322

(Registrant's telephone number, including area code)

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

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

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 April 27, 2023, 50,383,730 shares of the registrant's common stock, par value $0.0001 per share, were outstanding.

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Special Note Regarding Forward-Looking Statements

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

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

- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- the continued impact of the COVID-19 pandemic, and the related responses of the government and consumers on our business, financial condition and results of operations.

The forward-looking statements included herein are based on current expectations of our management based on available information and involve a number of risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond our control. As such, our actual results may differ significantly from those expressed in any forward-looking statements. Factors that may cause or contribute to such differences include, but are not limited to, those discussed in more detail in Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of Part I and Item 1A “Risk Factors” of Part II of this Quarterly Report on Form 10-Q. Readers should carefully review these risks, as well as the additional risks described in other documents we file from time to time with the Securities and Exchange Commission (SEC). In light of the significant risks and uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that such results will be achieved, and readers are cautioned not to place undue reliance on such forward-looking statements. Except as required by law, we undertake no obligation to revise the forward-looking statements contained herein to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. You should read this Quarterly Report on Form 10-Q and the documents we file with the SEC, with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

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

This Quarterly Report on Form 10-Q includes our trademarks and trade names, including, without limitation, Axonics R20™, Axonics F15™ and Bulkamid®, 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, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 240,105	$ 238,846
Short-term investments	116,957	118,365
Accounts receivable, net of allowance for credit losses of $322 and $321 at March 31, 2023 and December 31, 2022, respectively	40,200	44,817
Inventory, net	66,067	55,765
Prepaid expenses and other current assets	6,342	7,282
Total current assets	469,671	465,075
Property and equipment, net	7,017	6,798
Intangible assets, net	85,888	86,253
Other assets	6,534	6,813
Goodwill	96,581	94,414
Total assets	$ 665,691	$ 659,353
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 14,737	$ 9,070
Accrued liabilities	6,640	6,520
Accrued compensation and benefits	8,836	15,495
Operating lease liability, current portion	1,557	1,562
Other current liabilities	34,400	32,600
Total current liabilities	66,170	65,247
Operating lease liability, net of current portion	7,178	7,555
Deferred tax liabilities, net	15,737	16,412
Total liabilities	89,085	89,214
Commitments and contingencies (Note 3)		
Stockholders' equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, par value $0.0001, 75,000,000 shares authorized at March 31, 2023 and December 31, 2022; 50,110,667 and 49,546,727 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	982,189	969,545
Accumulated deficit	(383,512)	(374,264)
Accumulated other comprehensive loss	(22,076)	(25,147)
Total stockholders' equity	576,606	570,139
Total liabilities and stockholders' equity	$ 665,691	$ 659,353

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	**2022**
Net revenue	$ 70,650	$ 48,420
Cost of goods sold	18,150	15,178
Gross profit	52,500	33,242
Operating expenses		
Research and development	8,056	11,236
General and administrative	12,168	10,013
Sales and marketing	42,654	33,063
Amortization of intangible assets	2,222	2,463
Acquisition-related costs	1,766	—
Total operating expenses	66,866	56,775
Loss from operations	(14,366)	(23,533)
Other income (expense)		
Interest and other income	3,628	43
Interest and other expense	683	(289)
Other income (expense), net	4,311	(246)
Loss before income tax benefit	(10,055)	(23,779)
Income tax benefit	(807)	(1,111)
Net loss	(9,248)	(22,668)
Foreign currency translation adjustment	3,071	(4,920)
Comprehensive loss	$ (6,177)	$ (27,588)
Net loss per share, basic and diluted (see Note 1)	$ (0.19)	$ (0.50)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	48,579,084	45,139,038

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance at December 31, 2022	49,546,727	$ 5	$ 969,545	$ (374,264)	$ (25,147)	$ 570,139
Issuance of common stock for employee stock option exercises for cash	116,452	—	1,930	—	—	1,930
Restricted Shares Award (RSA) issuances and forfeitures for terminations, net and stock-based compensation	247,770	—	7,295	—	—	7,295
Issuance of common stock for vesting of Restricted Stock Units (RSU) and stock-based compensation	199,718	—	3,419	—	—	3,419
Foreign currency translation adjustment	—	—	—	—	3,071	3,071
Net loss	—	—	—	(9,248)	—	(9,248)
Balance at March 31, 2023	50,110,667	5	982,189	(383,512)	(22,076)	576,606

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance at December 31, 2021	46,330,167	$ 5	$ 803,559	$ (314,566)	$ (6,560)	$ 482,438
Issuance of common stock for employee stock option exercises for cash	91,286	—	1,444	—	—	1,444
RSA issuances and forfeitures for terminations, net and stock-based compensation	312,479	—	5,633	—	—	5,633
Issuance of common stock for vesting of RSU and stock-based compensation	268,930	—	1,505	—	—	1,505
Foreign currency translation adjustment	—	—	—	—	(4,920)	(4,920)
Net loss	—	—	—	(22,668)	—	(22,668)
Balance at March 31, 2022	47,002,862	5	812,141	(337,234)	(11,480)	463,432

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	**2022**
Cash Flows from Operating Activities		
Net loss	$ (9,248)	$ (22,668)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,813	3,029
Stock-based compensation	10,714	7,138
Provision for (reversal of) allowance of credit losses	1	(39)
Change in fair value of contingent consideration	1,800	—
Deferred income taxes and other items, net	(1,184)	(1,210)
Changes in operating assets and liabilities		
Accounts receivable	4,670	1,595
Inventory	(10,120)	3,015
Prepaid expenses and other current assets	850	1,474
Other assets	(134)	(25)
Accounts payable	5,593	2,529
Accrued liabilities	118	900
Accrued compensation and benefits	(6,663)	(4,925)
Lease liability	9	20
Net cash used in operating activities	(781)	(9,167)
Cash Flows from Investing Activities		
Purchases of property and equipment	(794)	(291)
Purchases of short-term investments	(52,309)	—
Proceeds from sales and maturities of short-term investments	53,797	—
Net cash provided by (used in) investing activities	694	(291)
Cash Flows from Financing Activities		
Proceeds from exercise of stock options	1,930	1,444
Net cash provided by financing activities	1,930	1,444
Effect of exchange rate changes on cash and cash equivalents	(584)	316
Net increase (decrease) in cash and cash equivalents	1,259	(7,698)
Cash and cash equivalents, beginning of year	238,846	220,878
Cash and cash equivalents, end of period	$ 240,105	$ 213,180
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ —	$ 1
Cash paid for taxes	$ —	$ —
Noncash Investing and Financing Activities		
Property and equipment acquired but not yet paid	$ 16	$ 267

See accompanying notes to unaudited condensed consolidated financial statements.

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

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

Nature of Operations

Axonics, Inc. (the Company) was incorporated in the state of Delaware on March 2, 2012 under the name American Restorative Medicine, Inc. 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. In August 2013, the Company changed its name to Axonics Modulation Technologies, Inc. In March 2021, the Company changed its name to Axonics, Inc.

The Company is a medical technology company that develops and commercializes innovative and minimally invasive products to treat bladder and bowel dysfunction. The Company has designed and developed both rechargeable (R20™) and recharge-free (F15™) implantable sacral neuromodulation (SNM) systems, which deliver 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 Company's products are protected by intellectual property based on Company-generated innovations and patents and other intellectual property licensed from AMF. The Company has marketing approvals in the United States, Europe, Canada, and Australia for all relevant clinical indications. The premarket approval (PMA) application for the rechargeable SNM system for the treatment of FI was approved by the U.S. Food and Drug Administration (FDA) on September 6, 2019, and the PMA application for the rechargeable SNM system for the treatment of OAB and UR was approved by the FDA on November 13, 2019. Accordingly, the Company began U.S. commercialization of its rechargeable SNM system in the fourth quarter of 2019.

Beginning in February 2021 with the acquisition of Contura Limited, the Company also markets Bulkamid®, a urethral bulking agent to treat female stress urinary incontinence (SUI). Beginning in March 2022 with the FDA approval of the Company's long-lived, recharge-free F15 SNM implantable stimulator, the Company now markets and sells the F15 recharge-free system to customers in the United States in addition to the rechargeable SNM system. The new recharge-free SNM system and Bulkamid are protected by intellectual property based on Company-generated innovations or patents acquired as part of the Contura acquisition.

August 2022 Follow-On Offering

On August 5, 2022, the Company completed a follow-on offering by issuing 2,012,500 shares of common stock, at an offering price of $63.85 per share, inclusive of 262,500 shares of the Company's common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The net proceeds to the Company were approximately $128.3 million, after deducting offering expenses payable by the Company.

Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements include the accounts of the Company; its wholly-owned subsidiaries: Axonics Europe, S.A.S., Axonics Modulation Technologies U.K. Limited, Axonics Modulation Technologies Australia Pty Ltd, Axonics Women's Health Limited, Bulkamid SARL, Axonics GmbH, and Contura, Inc. Intercompany accounts and transactions have been eliminated in consolidation.

Basis of Presentation and Liquidity

Interim Financial Statements

The unaudited interim condensed consolidated financial statements and related footnote disclosures as of and for the three months ended March 31, 2023 are unaudited, and are not necessarily indicative of the Company's operating results for a full year. The unaudited interim condensed consolidated financial statements include all normal and recurring adjustments necessary for a fair presentation of the Company's financial results for the three months ended March 31, 2023 in accordance with United States generally accepted accounting principles (GAAP), however, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the U.S. Securities and Exchange Commission (SEC) rules and regulations relating to interim financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial

statements and notes thereto included within the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (filed with the SEC on March 1, 2023).

Liquidity

The Company only began full-scale commercialization of the r-SNM System in late 2019. The Company has expended significant resources on research and development activities, growing its operations organization and building and training its sales organization.

The Company incurred net losses of $9.2 million and $22.7 million for the three months ended March 31, 2023 and 2022, respectively, and had an accumulated deficit of $383.5 million as of March 31, 2023 compared to $374.3 million at December 31, 2022. The Company expects to continue to spend a significant amount of its existing resources on sales and marketing activities as the Company continues to invest in commercializing and marketing its products in the United States and internationally.

As of March 31, 2023, the Company had cash, cash equivalents, and short-term investments of $357.1 million compared to $357.2 million at December 31, 2022. The Company expects that its cash, cash equivalents, and short-term investments on hand will be sufficient to fund its operations through at least the next 12 months. The Company funds its operations through a combination of proceeds from public offerings of its common stock and cash receipts from sales of its products. As of March 31, 2023, the Company had no outstanding borrowings.

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

Use of Estimates

The preparation of unaudited 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 disclosures of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates, and such differences may be material to the consolidated financial statements. Significant items subject to such estimates and assumptions include the useful lives of property and equipment and intangible assets, the valuation of deferred income tax assets and liabilities, the valuation of contingent consideration liability, the valuation of stock-based compensation, the product returns reserve, the inventory obsolescence reserve and accounts receivable allowance for credit losses.

Revenue Recognition

Revenue recognized during the three months ended March 31, 2023 and 2022 relates entirely to the sale of the Company's products to its customers and distributors.

The Company has revenue arrangements that consist of a single performance obligation. The Company recognizes revenue at the point in time when it transfers control of promised goods to its customers. Revenue is measured as the amount of consideration it expected to be received in exchange for transferring goods. The amount of revenue that is recognized is based on the transaction price, which represents the invoiced amount and includes estimates of variable consideration such as discounts, where applicable. The Company also sells to distributors and applies the same policies as its revenue arrangements with customers, specifically that revenue is recognized at the point in time when it transfers control of promised goods to its distributors. The Company does not offer rights of return or price protection. The amount of variable consideration included in the transaction price may be constrained and is included only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Payment terms, typically less than three months, do not include a significant financing component. The Company extends credit to its customers and

distributors based upon an evaluation of their financial condition and credit history and generally requires no collateral. The Company does not have any contract balances related to product sales. The Company also does not have significant contract acquisition costs related to product sales.

In accordance with Company policy and based on the Company's historical experience, the allowance for product returns was $0.2 million and $0.2 million at March 31, 2023 and December 31, 2022, respectively, and is recorded as a reduction of gross revenue in its unaudited condensed consolidated statements of comprehensive loss. Damaged or defective products are replaced at no charge under the Company's standard warranty. For the three months ended March 31, 2023 and 2022, the replacement costs were minimal and $0.1 million, respectively. The replacement costs are recorded within the sales and marketing expenses in its unaudited condensed consolidated statements of comprehensive loss.

The Company offers its standard warranty to all customers. The Company does not sell any warranties on a standalone basis. The Company's warranty provides that its products are free of material defects and conform to specifications, and includes an offer to repair, replace or refund the purchase price of defective products. This assurance does not constitute a service and is not considered a separate performance obligation. The Company estimates warranty liabilities at the time of revenue recognition and records it as a charge to sales and marketing expense. The warranty liability as of March 31, 2023 and December 31, 2022 was $0.1 million and $0.1 million, respectively.

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

The following table provides additional information pertaining to net revenue disaggregated by product and geographic market for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
SNM net revenue		
United States	$ 53,853	$ 37,715
International markets	1,305	1,355
	$ 55,158	$ 39,070
Bulkamid net revenue		
United States	$ 11,613	$ 6,569
International markets	3,879	2,781
	$ 15,492	$ 9,350
Total net revenue	$ 70,650	$ 48,420

Allowance for Credit Losses

The Company makes estimates of the collectability of accounts receivable in accordance with Accounting Standards Update (ASU) 2016-13, "Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." The Company's estimate of future credit losses is made by management based upon historical bad debts, customer receivable balances, age of customer receivable balances, customers' financial conditions and reasonable forecasted economic trends. Despite the Company's efforts to minimize credit risk exposure, customers could be adversely affected if future economic and industry trends change in such a manner as to negatively impact their cash flows. As a result, the Company's future collection experience can differ significantly from historical collection trends. If the Company's customers experience a negative impact on their cash flows, it could have a material adverse effect on the Company's results of operations and financial condition.

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

	Three Months Ended March 31,	
	2023	2022
Balance at beginning of period	$ 321	$ 355
Write-offs	—	—
Bad debt expense (recoveries)	1	(39)
Balance at end of period	$ 322	$ 316

Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments purchased with a maturity of three months or less. Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. At times, the cash and cash equivalent balances may exceed federally insured limits. The Company does not believe that this results in any significant credit risk as the Company's policy is to place its cash and cash equivalents in highly-rated financial institutions. The Company also holds cash in foreign banks that are not federally insured. The Company has not experienced any losses on its deposits of cash and cash equivalents.

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.

Level 1 investments include U.S. government and agency securities, which are valued based on prices readily available in the active markets in which those securities are traded. Level 2 investments include commercial paper and corporate notes, which is valued on a recurring basis based on inputs that are readily available in public markets or can be derived from information available in publicly quoted markets.

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 unaudited condensed consolidated financial statements approximate the fair value for cash and cash equivalents, accounts receivable, and accounts payables, due to their short-term nature.

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

Certain of the Company's business combinations involve potential payment of future consideration that is contingent upon the achievement of certain product development milestones and/or contingent on the acquired business reaching certain performance milestones. A liability is recorded for the estimated fair value of the contingent consideration on the acquisition date. The fair value of the contingent consideration is remeasured at each reporting period, and the change in fair value is recognized within operating expenses in the consolidated statements of comprehensive loss.

On February 25, 2021, the Company acquired Contura Limited and its Bulkamid product, a urethral

bulking agent indicated for the treatment of female SUI. In consideration for the acquisition, the Company paid approximately $141.3 million in cash and issued 1,096,583 shares of our common stock. The Company may pay an additional $35 million in the event Bulkamid sales in any consecutive 12-month period exceed $50 million (the Milestone) before December 31, 2024, with payment due within 50 business days following the quarter in which the Milestone has been met.

Contingent consideration represents contingent milestone, performance and revenue-sharing payment obligations related to acquisitions and is measured at fair value, based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration is estimated using a binary option-based approach with assumptions the Company believes would be made by a market participant. Significant inputs include projected revenues, discount rates, volatility factors and risk-free rates. The Company assesses these assumptions on an ongoing basis as additional data impacting the assumptions is obtained and any change in fair value of the contingent consideration is recorded within acquisition-related costs in the consolidated statements of comprehensive loss. Significant increases or decreases in any of those inputs in isolation would result in a significantly lower or higher fair value measurement. Generally, a change in the assumption used for the projected revenues would result in a directionally similar change to the overall estimate of the contingent consideration. At March 31, 2023, the Milestone has been met. The fair value of contingent consideration of $34.4 million and $32.6 million at March 31, 2023 and December 31, 2022, respectively, is reflected in other current liabilities in the Company's unaudited condensed consolidated balance sheets.

The following table summarizes the changes in the fair value of recurring Level 3 fair value measurements during the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Liabilities		
Contingent consideration:		
Balance at beginning of period	$ 32,600	$ 10,370
Change in fair value included in earnings	1,800	—
Balance at end of period	$ 34,400	$ 10,370

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

Investment Securities

The Company classifies its investment securities as available-for-sale. Those investments in debt securities with maturities less than 12 months at the balance sheet date are considered short-term investments. Those investments in debt securities with maturities greater than 12 months at the balance sheet date are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based on the fair value hierarchy (Level 1 and Level 2 inputs in the fair value hierarchy), and consists primarily of commercial paper, corporate notes and U.S. government and agency securities. Unrealized gains or losses, deemed temporary in nature, are reported as other comprehensive income (loss) within the unaudited condensed consolidated statements of comprehensive loss. There were no unrealized gains or losses during the three months ended March 31, 2023 and 2022.

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 credit loss allowance 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, accretion and interest income are recognized when earned. Realized gains or losses are included in net loss and are derived using the specific identification method for determining the cost of securities sold.

The following table presents the fair value hierarchy for those assets measured at fair value on a recurring basis as of March 31, 2023 and December 31, 2022 (in thousands):

	Fair Value Measurements at March 31, 2023			
Assets:	**Level 1**	**Level 2**	**Level 3**	**Total**
Commercial paper	$ —	$ 50,693	$ —	$ 50,693
Corporate notes	—	4,181	—	4,181
U.S. government and agency securities	114,683	—	—	114,683
	$ 114,683	$ 54,874	$ —	$ 169,557

(1) As of March 31, 2023, commercial paper investments of $14.9 million and U.S. government and agency securities of $37.7 million are included in cash and cash equivalents on the unaudited condensed consolidated balance sheets, as the investments had a maturity of three months or less from the date of purchase on the unaudited condensed consolidated balance sheets.

	Fair Value Measurements at December 31, 2022			
Assets:	**Level 1**	**Level 2**	**Level 3**	**Total**
Commercial paper	$ —	$ 175,548	$ —	$ 175,548
Corporate notes	—	4,675	—	4,675
U.S. government and agency securities	75,212	—	—	75,212
	$ 75,212	$ 180,223	$ —	$ 255,435

(1) As of December 31, 2022, commercial paper investments of $131.1 million, U.S. government and agency securities of $4.0 million, and corporate notes of $2.0 million are included in cash and cash equivalents on the unaudited condensed consolidated balance sheets, as the investments had a maturity of three months or less from the date of purchase on the unaudited condensed consolidated balance sheets.

The Company holds investments in marketable debt securities that are classified and accounted for as cash equivalents or available-for-sale and are remeasured on a recurring basis. All of the Company's available-for-sale debt securities are classified on the unaudited condensed consolidated balance sheets as cash equivalents or short-term investments. The following table summarizes the Company's cash equivalents and investments in available-for-sale debt securities by significant investment category as of March 31, 2023 and December 31, 2022 (in thousands):

	March 31, 2023			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash equivalents:				
Commercial paper	$ 14,943	$ —	$ —	$ 14,943
Corporate notes	—	—	—	—
U.S. government and agency securities	37,657	—	—	37,657
Total cash equivalents	$ 52,600	$ —	$ —	$ 52,600
Short-term investments:				
Commercial paper	$ 35,750	$ —	$ —	$ 35,750
Corporate notes	4,182	2	(3)	4,181
U.S. government and agency securities	77,055	20	(49)	77,026
Total short-term investments	$ 116,987	$ 22	$ (52)	$ 116,957
Total	$ 169,587	$ 22	$ (52)	$ 169,557

	December 31, 2022			
	Cost	Unrealized gains	Unrealized losses	Fair value
Cash equivalents:				
Commercial paper	$ 131,075	$ —	$ —	$ 131,075
Corporate notes	2,013	—	—	2,013
U.S. government and agency securities	3,982	—	—	3,982
Total cash equivalents	$ 137,070	$ —	$ —	$ 137,070
Short-term investments:				
Commercial paper	$ 44,473	$ —	$ —	$ 44,473
Corporate notes	2,664	—	(2)	2,662
U.S. government and agency securities	71,342	6	(118)	71,230
Total short-term investments	$ 118,479	$ 6	$ (120)	$ 118,365
Total	$ 255,549	$ 6	$ (120)	$ 255,435

Foreign Currency Translation

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Revenue and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' equity in accumulated other comprehensive gain or loss until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss). As of March 31, 2023 and December 31, 2022, all foreign currency translation gains (losses) have been unrealized and included in accumulated other comprehensive loss. Accumulated other comprehensive loss consists entirely of losses or gains from translation of foreign subsidiaries at March 31, 2023 and December 31, 2022.

Inventory, Net

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

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

Products that have been approved by certain regulatory authorities may also be used in clinical programs to assess the safety and efficacy of the products for usage that have not been approved by the FDA or other regulatory authorities. The form of product utilized for both commercial and certain clinical programs that are identical are included as inventory with an "alternative future use" as defined in authoritative guidance. Component materials and purchased products associated with clinical development programs are included in inventory and charged to research and development expenses 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 expenses 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 Company's SNM systems is subject to strict quality control, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to the Company's inventory values. The Company also applies judgment related to the results of quality tests that are performed throughout the production process, as well as the understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre- and post-production processes, and the Company continually gathers information regarding product quality for periods after the manufacturing date. The Company's products currently have a maximum estimated shelf life range of 12 to 36 months and based on sales forecasts, the Company expects to realize the carrying value of the product inventory. In the future, reduced demand, quality issues, or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

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

As of March 31, 2023, the Company had $35.4 million, $7.4 million and $23.3 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, net of reserves of $0.4 million. As of December 31, 2022, the Company had $30.4 million, $5.7 million and $19.7 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, net of reserves of $0.5 million.

Customer and Vendor Concentration

As of March 31, 2023 and December 31, 2022, there were no customers who accounted for over 10% of the Company's consolidated accounts receivable. As of March 31, 2023 and December 31, 2022, there were two vendors and one vendor, respectively, who accounted for over 10% of the Company's consolidated accounts payable. During the three months ended March 31, 2023 and 2022, there were no customers who accounted for over 10% of the Company's consolidated net revenue. During the three months ended March 31, 2023 and 2022, there were three vendors and three vendors, respectively, who accounted for over 10% of the Company's inventory-related purchases.

Property and Equipment

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

Goodwill

Goodwill represents the excess purchase price over the fair values of both tangible and intangible assets acquired less the liabilities assumed. Goodwill is tested for impairment at the reporting unit level by comparing the reporting unit's carrying amount to the fair value of the reporting unit. The fair values are estimated using an income and discounted cash flow approach. The Company evaluates its goodwill on an annual basis in the fourth quarter or more frequently if it believes indicators of impairment exist. The Company assesses qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount or performs an annual impairment test. When tested quantitatively, the Company compares the fair value of the applicable reporting unit with its carrying value. In making this assessment, management relies on a number of factors, including expected future operating results, business plans, economic projections, anticipated future cash flows, business trends and declines in the Company's market capitalization. The Company estimates the fair value of its reporting unit using a combination of the discounted cash flow and income approaches. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the amount by which the carrying value exceeds the fair value is recognized as an impairment loss. During the three months ended March 31, 2023, the Company did not record any impairment charges related to goodwill.

Intangible Assets

Patent license asset

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The additional field-of-use was provided in exchange for 50,000 shares of Series A preferred stock, the fair value of which was $1.0 million in 2013. The intangible asset was recorded at its fair value of $1.0 million at the date contributed. In connection with the initial public offering, such shares of Series A preferred stock were converted into common stock. Amortization of this asset is recorded over the shorter of the patent or legal life on a straight-line basis. The weighted-average amortization period is 8.71 years. The asset has been fully amortized as of March 31, 2023. For additional information, see Note 7.

Exclusive license asset

The intangible asset represents exclusive rights to existing technologies and development services from Micro Systems Engineering, Inc. pursuant to an agreement entered into on March 2, 2021. The rights and services were provided in exchange for 65,594 shares of common stock, the fair value of which was $3.6 million upon transfer. The intangible asset was recorded at its fair value of $3.3 million at the date of the agreement, with the difference of $0.3 million recorded as a vendor credit in accounts payable in the unaudited condensed consolidated balance sheets. Amortization of this asset is recorded over the four-year term of the agreement on a straight-line basis. The Company recorded expense for the amortization of the exclusive license asset of $0.2 million during the three months ended March 31, 2023 and 2022. The Company will review the intangible asset for impairment whenever an impairment indicator exists. There have been no intangible asset impairment charges to date. For additional information, see Note 7.

Contura acquisition

The intangible assets represent technology, trade names and trademarks, and customer relationships acquired from Contura on February 25, 2021. The trade names and trademarks have an indefinite life. The straight-line method over the period of estimated benefit is used to amortize technology. Accounting Standards Codification (ASC) 350-30-35-3 states that customer relationships generally dissipate at a more rapid rate in the earlier periods following a company's succession to these relationships, with the rate of attrition declining over time. As such, the accelerated method is used to amortize customer relationships. The Company recorded expense for the amortization of Contura acquisition intangible assets of $2.1 million and $2.2 million during the three months ended March 31, 2023 and 2022, respectively. The Company reviewed the intangible assets for impairment for this asset group during the three months ended March 31, 2023. As Bulkamid SARL ceased sales operations and did not recognize revenue during the year ended December 31, 2022, and does not expect to recognize revenue in future periods, the Company wrote off the customer relationships intangible asset of $0.3 million related to this entity during the year ended December 31, 2022. The impairment expense is recorded within the general and administrative expenses in its unaudited condensed consolidated statements of comprehensive loss. For additional information, see Note 7.

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 $0.3 million of impairments of long-lived assets to date.

Indefinite-lived intangible assets are tested for impairment annually in the fourth quarter of the fiscal year and whenever events or changes in circumstances indicate that the carrying amount may be impaired. Impairment is calculated as the excess of the asset's carrying value over its fair value. Fair value is generally determined using a discounted future cash flow analysis. There have been no impairments to indefinite-lived intangible assets during the three months ended March 31, 2023.

Leases

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

between operating and finance leases. The aforementioned bright lines are applied consistently to the Company's entire portfolio of leases.

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

Research and Development

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

Advertising Expense

The Company expenses advertising costs as they are incurred. During the three months ended March 31, 2023 and 2022, advertising expense totaled $4.3 million and $3.2 million, respectively, and are recorded within the sales and marketing expenses in its unaudited condensed consolidated statements of comprehensive loss.

Income Taxes

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

Stock-Based Compensation

The Company measures the cost of employee and non-employee services in exchange for an award of equity instruments based on the grant-date fair value of the award and recognizes compensation cost over the requisite service period (typically the vesting period), generally three or four years. Forfeitures are estimated at the time of the grant and revised in subsequent periods to reflect differences between the estimates and the number of shares that actually become exercisable.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options (as of the date of grant) that have service conditions for vesting. Stock options and restricted shares awards vest based on service conditions, typically over three or four years.

The Company also grants shares of performance-based restricted stock units that typically vest after one year only if the Company has also achieved certain performance objectives as defined and approved by the Company's board of directors. The fair value of performance awards is determined based on the Company's stock price at the date of grant and expensed over the performance period based on the probability of achieving the

performance objectives. If such targets are not met or service is not rendered for the requisite service period, no compensation cost is recognized, and any recognized compensation cost in prior periods will be reversed. In addition, the Company also grants market-based restricted stock units that have combined market conditions and service conditions for vesting, for which the Company uses the Monte Carlo valuation model to value equity awards (as of the date of grant). Compensation cost is not adjusted if the market condition is not met, as long as the requisite service is provided.

Net Loss per Share of Common Stock

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

For the three months ended March 31, 2023 and 2022, there were 2,163,018 and 2,416,373 potentially dilutive weighted-average shares, respectively, that were not included in the computation of diluted weighted-average shares of common stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss.

Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined it operates in one segment, the development and commercialization of innovative and minimally invasive products to treat bladder and bowel dysfunction. Geographically, the Company sells over 90% of its products to customers in the United States. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

Recent Accounting Pronouncements

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

Note 2. Property and Equipment, Net

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

	March 31, 2023	December 31, 2022
Equipment	$ 2,772	$ 2,645
Computer hardware and software	3,282	3,282
Tools and molds	1,980	1,735
Leasehold improvements	4,449	4,449
Furniture and fixtures	1,810	1,810
Construction in progress	845	413
	15,138	14,334
Less: accumulated depreciation and amortization	(8,121)	(7,536)
	$ 7,017	$ 6,798

Depreciation and amortization expense of property and equipment was $0.6 million and $0.6 million for the three months ended March 31, 2023 and 2022, respectively.

Note 3. Commitments and Contingencies

Operating Leases

In August 2014, the Company entered into a five-year operating lease for approximately 12,215 square feet of office space beginning on November 1, 2014, and expiring on October 31, 2019. In June 2019, the lease was amended to extend the expiration date to October 31, 2020. In September 2020, the lease was amended to extend the expiration date to July 31, 2022, and in December 2021, the lease was amended to extend the expiration date to January 31, 2028. Upon the execution of the amendments, which were deemed to be a lease modification, the Company reassessed the lease liability using the incremental borrowing rate for a collateralized asset of the same remaining term at the modification date and recorded ROU assets for the same amount. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term.

The Company entered into an operating lease for approximately 25,548 square feet of office space beginning on August 1, 2018, and expiring on October 31, 2027. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term. The Company has a renewal option to extend the term of the lease for a period of five years beyond the initial term. Under the terms of the lease, the base rent payable with respect to each renewal term will be equal to the prevailing market rental rent as of the commencement of the applicable renewal term. In the event of a default of certain of the Company's obligations under the lease, the Company's landlord would have the right to terminate the lease.

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

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

In March 2022, the Company entered into an 18-month operating lease for approximately 3,276 square feet of warehouse space beginning on July 1, 2022 and expiring on December 31, 2023. The Company uses these premises for general warehouse space.

During the three months ended March 31, 2023 and 2022, there were no ROU assets obtained in exchange for new operating lease liabilities. As of March 31, 2023 and December 31, 2022, the ROU assets had a balance of $5.9 million and $6.2 million, respectively. The operating lease ROU assets are included within the Company's non-current other assets, and lease liabilities are included in current or noncurrent liabilities in the Company's unaudited condensed consolidated balance sheets. During the three months ended March 31, 2023 and 2022, cash paid for amounts included in operating lease liabilities was $0.5 million and $0.5 million, respectively. Amortization of the ROU assets was $0.3 million and $0.2 million for the three months ended March 31, 2023 and 2022, respectively.

As of March 31, 2023 and December 31, 2022, the weighted-average remaining lease term for the Company's operating leases was 4.7 years and 4.9 years, respectively. The weighted-average incremental borrowing

rate for a collateralized asset of the same remaining term used to determine the present value of the Company's operating leases' future payments was 7.1% and 7.1%, respectively.

Total lease costs for the three months ended March 31, 2023 and 2022 are as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Lease cost		
Operating lease cost	$ 542	$ 524
Short-term lease cost	23	21
Variable lease cost	40	35
Total lease cost	$ 605	$ 580

License Agreement

In October 2013, the Company entered into the License Agreement, pursuant to which AMF, a Company stockholder, licensed the Company certain patents and know-how (collectively, the AMF IP) relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (collectively, the AMF Licensed Products). Under the License Agreement, for each calendar year beginning in 2018, the Company is obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to the Company by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) the Minimum Royalty, payable quarterly. The Minimum Royalty automatically increases each year after 2018, subject to a maximum amount of $200,000 per year. The Company recorded related royalties of $0.3 million and $1.6 million during the three months ended March 31, 2023 and 2022, respectively. Royalty expense is included in operating expenses in the unaudited condensed consolidated statements of comprehensive loss. Accrued royalties of $0.3 million and $0.6 million as of March 31, 2023 and December 31, 2022, respectively, are included within accrued liabilities in the Company's unaudited condensed consolidated balance sheets. Royalty expense is declining because the Company's F15 recharge-free SNM device is not covered by any AMF patents licensed to the Company and is therefore not an AMF Licensed Product that requires the payment of a royalty to AMF.

Legal Matters

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

claims, the Medtronic Litigation could result in significant costs, delays in future product developments, reputational harm or other collateral consequences. The Company is currently engaged in discovery in the Medtronic Litigation. A jury trial is scheduled in the Medtronic Litigation for August 2023.

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

Note 4. Stock-Based Compensation

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

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 2,204	$ 1,510
General and administrative	2,826	1,937
Sales and marketing	5,684	3,691
	$ 10,714	$ 7,138

Stock Option Activity

The option awards issued under the 2014 Stock Option Plan (the 2014 Plan) and the 2018 Omnibus Incentive Plan (the 2018 Plan) were measured based on fair value. The Company used the simplified method of determining the expected term of stock options as the Company believes this represents the best estimate of the expected term of a new option. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have sufficient trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments, whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The assumptions regarding the expected term of the options and the expected volatility of the stock price are subjective, and these assumptions have a significant effect on the estimated fair value amounts. There were no stock option grants for the three months ended March 31, 2023 and 2022.

As of March 31, 2023 and December 31, 2022, there was $1.1 million and $1.8 million, respectively, of total unrecognized compensation cost related to unvested stock options that is expected to be recognized over a weighted-average period of approximately 0.9 years and 1.0 year, respectively.

The following table summarizes stock option activity for the three months ended March 31, 2023 under the 2014 and 2018 Plans (in thousands, except share and per share data):

	Number of Options	Weighted-Average Exercise Price Per Share	Aggregate Intrinsic Value	
Outstanding at December 31, 2022	1,046,610	$ 18.81		
Options exercised	(116,452)	16.58	$ 5,451	(1)
Options forfeited	(261)	27.10		
Outstanding at March 31, 2023	929,897	$ 19.08	$ 33,127	(2)

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

(2) Represents the total difference between the Company's closing stock price on the last trading day of the first quarter of 2023 and the stock option exercise price, multiplied by the number of in-the-money options as of March 31, 2023. The amount of intrinsic value will change based on the fair market value of the Company's stock.

The weighted-average remaining contractual term of options outstanding and exercisable was 5.9 years and 6.1 years at March 31, 2023 and December 31, 2022, respectively.

Restricted Shares Awards Activity

As of March 31, 2023 and December 31, 2022, there was $61.8 million and $54.0 million, respectively, of total unrecognized compensation cost related to unvested restricted shares awards that is expected to be recognized over a weighted-average period of approximately 2.3 years and 2.3 years, respectively.

The following table summarizes restricted shares awards activity for the three months ended March 31, 2023:

	Number of Restricted Shares Awards	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2022	1,320,866	$ 52.23
Restricted shares awards granted	278,816	58.33
Restricted shares awards vested	(275,851)	41.61
Restricted shares awards forfeited	(31,046)	56.16
Outstanding at March 31, 2023	1,292,785	$ 55.72

Restricted Stock Units Activity

As of March 31, 2023 and December 31, 2022, there was $14.9 million and $1.3 million, respectively, of total unrecognized compensation cost related to unvested restricted stock units that is expected to be recognized over a weighted-average period of approximately 1.2 years and 0.8 years, respectively.

The following table summarizes restricted stock units activity for the three months ended March 31, 2023:

	Number of Restricted Stock Units	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2022	183,418	$ 48.74
Restricted stock units granted	286,750	65.44
Restricted stock units vested	(199,718)	49.84
Outstanding at March 31, 2023	270,450	$ 70.10

Note 5. Income Taxes

The following table presents details of the provision for income taxes and effective tax rates (in thousands, except percentages):

	Three Months Ended March 31,	
	2023	2022
Income tax benefit	$(807)	$(1,111)
Effective tax rate	8.02%	4.67%

The Company accounts for income taxes according to ASC 740, “Income Taxes.” The Company periodically evaluates whether a portion or all of its deferred tax assets will be recovered. The Company records a valuation allowance against deferred tax assets if and to the extent it is more likely than not that they will not be recovered. In evaluating the need for a valuation allowance, the Company weighs all relevant positive and negative evidence, including among other factors, historical financial performance, forecasts of income over the applicable carryforward periods, and the market environment, with each consideration weighted based on its reliability. The Company continues to maintain a full valuation allowance against its otherwise recognizable U.S. net deferred income tax assets as of March 31, 2023 and December 31, 2022.

The effective tax rate differs from the statutory U.S. income tax rate due to differing tax rates imposed on income earned in foreign jurisdictions, losses in foreign jurisdictions, and certain nondeductible expenses. The effective tax rate could change significantly from quarter to quarter because of recurring and nonrecurring factors. The provision for income taxes for the three months ended March 31, 2023 was primarily the result of losses benefited in certain foreign jurisdictions.

At December 31, 2022, the Company had U.S. federal and foreign net operating loss (NOL) carryforwards of approximately $270.3 million and $9.6 million, respectively. U.S. federal NOLs in the amount of $51.5 million will expire between 2033 and 2037 while the remainder will carryover indefinitely. The foreign net operating loss carryforwards have an indefinite carryforward period. The Company had U.S. state NOLs of $254.6 million, which will expire between 2033 and 2042.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code), use of the Company’s NOL carryforwards may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a rolling three-year period. The Company performed an analysis of changes in ownership for purposes of these Internal Revenue Code sections. Based on the study performed in 2020, the Company determined that an ownership change occurred in 2014, 2018 and 2019. The total reduction of the net operating loss carryforwards was offset by valuation allowance, and there was no impact to tax expense related to

the limitation. Based on the study performed in 2022 and 2021, the Company determined that an ownership change did not occur in 2022 and 2021. Future ownership changes could impact the Company's ability to utilize NOL carryforwards.

Note 6. 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 U.S. 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 months ended March 31, 2023 and 2022, the Company contributions to the plan amounted to $0.6 million and $0.5 million, respectively.

Note 7. Goodwill and Intangible Assets

The change in the carrying amount of goodwill during the three months ended March 31, 2023 included the following (in thousands):

December 31, 2022	$	94,414
Foreign currency translation adjustment		2,167
March 31, 2023	$	96,581

Intangible assets as of March 31, 2023 included the following (in thousands):

		March 31, 2023				
	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Impairment	Foreign currency translation adjustment	Intangible Assets, Net
Patent license asset	8.71 years	$ 1,000	$ (1,000)	$ —	$ —	$ —
Exclusive license asset	4 years	3,300	(1,760)	—	—	1,540
Technology	12 years	81,100	(14,147)	—	(7,815)	59,138
Trade names and trademarks	Indefinite	19,700	—	—	(2,001)	17,699
Customer relationships	12 years	11,400	(2,744)	(287)	(858)	7,511
		$ 116,500	$ (19,651)	$ (287)	$ (10,674)	$ 85,888

Intangible assets as of December 31, 2022 included the following (in thousands):

		December 31, 2022				
	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Impairment	Foreign currency translation adjustment	Intangible Asset, Net
Patent license asset	8.71 years	$ 1,000	$ (1,000)	$ —	$ —	$ —
Exclusive license asset	4 years	3,300	(1,540)	—	—	1,760
Technology	12 years	81,100	(12,496)	—	(9,141)	59,463
Trade names and trademarks	Indefinite	19,700	—	—	(2,398)	17,302
Customer relationships	12 years	11,400	(2,393)	(287)	(992)	7,728
		$ 116,500	$ (17,429)	$ (287)	$ (12,531)	$ 86,253

Note 8. Subsequent Events

Acquisition of a technology asset from Radian, LLC

In April 2023, the Company acquired a technology asset from Radian, LLC (the Seller), for total consideration of the issuance of 264,783 shares of common stock and a potential future milestone payment of up to $2.5 million. The initial accounting for the asset purchase is incomplete as a result of the timing of the acquisition.

Lease

In April 2023, the Company entered into a Lease, by and between Sand Canyon Business Center I LLC (the Landlord) and the Company (the Lease), to lease certain premises located at 15515-15525 Sand Canyon Avenue, Irvine, California 92618 (the Sand Canyon Premises).

Pursuant to the Lease, the Company leases the Sand Canyon Premises for a 120-month term (the Initial Term) beginning in April 2024. The Company will pay monthly basic rent for the Sand Canyon Premises ranging from $0.3 million to $0.4 million over the Initial Term; provided, that for the first six months after the Commencement Date, the Company will be entitled to abatement of the monthly basic rent, or $0.3 million per month, if the Company is not in default under the Lease. In connection with the Lease, the Company delivered to

Landlord a cash security deposit of $1.6 million. In the event that the Company has positive earnings before interest, taxes and amortization during the twelve-month period preceding the 49th month of the Lease, Landlord will return to the Company $0.4 million of the security deposit in each of the 49th, 50th and 51st months of the Lease in the form of credits against basic rent. Under the Lease, the Company is also required to pay its share of operating expenses for the Sand Canyon Premises, which are currently estimated to be approximately $0.1 million per month.

Under certain circumstances, the Company also has the right to extend the Lease for the Sand Canyon Premises for an additional 60-month term.

Pursuant to the Lease, Landlord agreed to pay for up to $8.5 million of tenant improvements.

In addition, in April 2023, the Company entered into a Third Amendment to Lease (the Third Amendment), by and between the Company and The Irvine Company LLC (Irvine Company), with respect to the Company's premises at 18 Technology Drive (the 18 Technology Premises). Pursuant to the Third Amendment, the Company and Irvine Company agreed to extend the lease term for the 18 Technology Premises to expire on December 31, 2024.

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

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q, as well as the audited consolidated financial statements and the related notes thereto, and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the SEC on March 1, 2023.

Overview

We are a global medical technology company that is developing and commercializing novel products for adults with bladder and bowel dysfunction, including: (i) implantable rechargeable sacral neuromodulation (SNM) systems to treat urinary urge incontinence (UUI) and urinary urgency frequency (UUF), together referred to as overactive bladder (OAB), as well as fecal incontinence (FI), and non-obstructive urinary retention (UR); and (ii) a urethral bulking agent (Bulkamid) to treat female stress urinary incontinence (SUI).

SNM Systems

Our newly developed rechargeable SNM system, Axonics R20, is designed to last 20 or more years in the human body and is only 5cc in volume. R20 provides constant current stimulation and offers broad MRI access with 1.5T and 3.0T scanners. R20 utilizes an easy-to-use, intuitive patient remote control and requires recharging for only one hour every 6 to 10 months, which is the longest interval between recharging among rechargeable SNM systems. The R20 replaces the previous rechargeable SNM system offered by Axonics that was the first to be marketed worldwide.

Our recharge-free SNM system, Axonics F15, utilizes a primary cell battery with an expected life of 15 years at typical stimulation parameters and over 20 years at lower amplitude settings. The recharge-free implantable neurostimulator (INS) is approximately 10cc in volume, utilizes constant current stimulation, a recharge-free patient remote control and offers broad MRI access.

We began U.S. commercialization in the middle of the fourth quarter of 2019 after receiving premarket approval (PMA) of our first rechargeable SNM system by the FDA. We also have marketing approvals from regulators in Europe, Canada, and Australia for all relevant clinical indications.

SNM therapy has been commercially available in the United States for over 20 years and has been clinically proven to provide a safe, effective, reversible, and long-lasting symptom relief. We believe that our SNM systems offer therapeutic benefits and competitive advantages compared to the InterStim SNM systems offered by Medtronic.

We engineered our SNM systems to deliver constant-current stimulation, which automatically adjusts stimulation based on changes to impedance that occur as the implanted lead scars into the body, which we believe provides a more consistent therapy over time and reduces management of the therapy. Our SNM systems include an

easy-to-use wireless patient remote control that does not require recharging or replacement batteries. We also designed and custom built a clinician programmer that guides the implanting physician through lead placement and stimulation programming.

We continue to invest in research and development activities to expand our suite of products for SNM therapy. In March 2022, we received FDA approval for the Axonics F15, a long-term, recharge-free SNM system. In January 2023, we received FDA approval for the Axonics R20, our fourth-generation rechargeable SNM system.

We focus most of our sales and marketing efforts in the United States where reimbursement for SNM therapy is well-established and covered by most major U.S. insurers and Medicare.

Urethral Bulking Agent

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

SUI is a common condition that afflicts women of all ages, with childbirth as one of the main contributing factors. SUI is caused by weakness in the pelvic floor, preventing the urethra from closing fully when sudden pressure is put on the bladder. This can allow urine to leak out during normal daily activities such as coughing, laughing, exercising, or lifting an object.

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

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

Bulkamid is biocompatible, consisting of 97.5% water, and does not induce a chronic inflammatory response. Bulkamid's bulking effect is aided by the volume of each injection being predictable, controllable, and precise. Bulkamid retains its bulking characteristics for a number of years, thereby maintaining efficacy and providing women with long lasting relief of their SUI symptoms. Bulkamid is clinically validated and generates high rates of patient satisfaction.

Our Markets

The market for SNM therapy is large and growing, with approximately 19 million women in the United States having moderate to severe UUI or mixed urinary incontinence (MUI) symptoms, which is urinary incontinence related to both urgency and stress. Before treating patients with a third-line therapy such as SNM, physicians are required to prescribe first- and second-line therapies. First-line therapies include behavioral changes such as diet and exercise, and second-line therapies include drug therapy. We believe the SNM market will continue to expand for the foreseeable future driven by increased awareness and education of SNM therapy, greater expectations for quality of life, and improved patient attitudes toward receiving medical attention. In addition, market growth is anticipated due to continued innovation and the introduction of new efficacious and long-lived products for SNM therapy. We believe that this represents a compelling opportunity for our SNM systems to capture market share and grow the market for SNM therapy.

The market for SUI therapy is highly underpenetrated, with approximately 22 million women in the United States having moderate to severe SUI or MUI symptoms. The first-line treatment options for SUI begin with lifestyle changes and continence pessaries. SUI lacks pharmacologic treatments, with patients next advancing to urethral bulking agents, pelvic floor sling surgery or colposuspension. We estimate that less than half of these women have sought medical treatment, most of whom were offered conservative therapy or opted for no treatment due to a lack of non-invasive treatment options with high efficacy.

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

In the United States, the cost required to treat each patient is reimbursed through various third-party payors, such as commercial payors and government agencies. Most large insurers have established coverage policies in place to cover SNM therapy. Certain commercial payors have a patient-by-patient prior authorization process that must be followed before they will provide reimbursement for SNM therapy. Outside the United States, reimbursement levels vary significantly by country and by region, particularly based on whether the country or region at issue maintains a single-payor system. SNM therapy is eligible for reimbursement in Canada, Australia and certain countries in Europe. Annual healthcare budgets generally determine the number of SNM systems that will be paid for by the payor in these single-payor system countries and regions. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. Some countries or regions may require us to gather additional clinical data before granting coverage and reimbursement for our SNM systems.

We are currently engaged in the manufacturing of a number of processes of our SNM systems and outsource the manufacture of certain implantable components of our SNM systems with contract manufacturers who all have quality systems established that meet FDA requirements and are all recognized in their field for their competency to manufacture the respective portions of our SNM systems. We believe the manufacturers we currently utilize have sufficient capacity to meet our requirements and are able to scale up their capacity relatively quickly with limited capital investment.

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

We incurred net losses of $9.2 million and $22.7 million for the three months ended March 31, 2023 and 2022, respectively, and had an accumulated deficit of $383.5 million as of March 31, 2023 compared to $374.3 million at December 31, 2022. As of March 31, 2023, we had available cash, cash equivalents, and short-term investments of approximately $357.1 million, current liabilities of approximately $66.2 million, and long-term liabilities of approximately $22.9 million.

August 2022 Follow-On Offering

On August 5, 2022, we completed a follow-on offering by issuing 2,012,500 shares of common stock, at an offering price of $63.85 per share. The gross proceeds to us from this follow-on offering were $128.5 million and the net proceeds were approximately $128.3 million, after deducting offering expenses payable by us.

Components of Our Results of Operations

Net Revenue

Revenue during the three months ended March 31, 2023 and 2022 are as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
SNM net revenue		
United States	$ 53,853	$ 37,715
International markets	1,305	1,355
	$ 55,158	$ 39,070
Bulkamid net revenue		
United States	$ 11,613	$ 6,569
International markets	3,879	2,781
	$ 15,492	$ 9,350
Total net revenue	$ 70,650	$ 48,420

We expect our revenue to fluctuate from quarter to quarter due to a variety of factors, including seasonality. For example, the industry generally experiences lower revenues in the first and third quarters of the year and higher revenues in the fourth quarter. Our revenue has been impacted by these industry trends.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of costs of the components of our SNM systems, third-party contract labor costs, overhead costs, Bulkamid product costs, as well as distribution-related expenses such as logistics and shipping costs. The overhead costs include the cost of material procurement and operations supervision and management personnel. We expect overhead costs as a percentage of revenue to decrease as our sales volume increases. Cost of goods sold also include other expenses such as scrap and inventory obsolescence. We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our revenue grows. We expect gross margin to vary based on manufacturing costs, regional differences in pricing, and discounts negotiated by customers.

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

Research and Development Expenses

Research and development expenses consist primarily of employee compensation, including stock-based compensation, product development, including testing and engineering, royalty expense, and clinical studies to develop and support our SNM systems, including clinical study and registry management and monitoring, payments to clinical investigators, and data management. Other research and development expenses include consulting and advisory fees, royalty expense, travel expenses, and equipment-related expenses and other miscellaneous office and facilities expenses related to research and development programs. Research and development costs are expensed as incurred. We expect to continue incurring research and development expenses in the future as we develop new products 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 months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Personnel related	$ 5,606	$ 5,137
Clinical development	134	268
Contract R&D and manufacturing	1,727	3,956
Royalty expense	307	1,555
Other R&D expenses	282	320
Total R&D expenses	$ 8,056	$ 11,236

General and Administrative Expenses

General and administrative expenses consist primarily of employee compensation, including stock-based compensation, and spending related to finance, information technology, human resource functions, consulting, legal, and professional service fees. Other general and administrative expenses include director and officer insurance premiums, investor relations costs, office-related expenses, facilities and equipment rentals, bad debt expense, travel expenses, and impairment 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. Additionally, we anticipate increased legal expenses associated with our patent infringement litigation with Medtronic. We expect general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of employee compensation, including sales personnel commissions and stock-based compensation, direct-to-consumer advertising programs, trade shows, booth exhibition costs, and the related travel for these events. Other sales and marketing expenses include consulting and advisory fees. We expect sales and marketing expenses to continue to increase in absolute dollars as we continue to expand our commercial infrastructure to both drive and support our expected growth in revenue. However, we expect sales and marketing expenses to decrease as a percentage of revenue in the long term primarily as, and to the extent, our revenue grows.

Amortization of Intangible Assets

Amortization of intangible assets consist primarily of amortization expense on patent license asset, manufacturing license asset, technology, and customer relationships intangible assets. We amortize finite lived intangible assets over the period of estimated benefit using the straight-line method.

Acquisition-Related Costs

Acquisition-related costs consist of expenses incurred and changes in contingent consideration related to the Contura acquisition.

Other Income (Expense), Net

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

Income Tax Expense (Benefit)

Income tax expense (benefit) primarily consists of losses benefited in certain foreign jurisdictions. We maintain a full valuation allowance for deferred tax assets in our domestic operations, including net operating loss carryforwards and research and development credits.

Results of Operations

The following table shows our results of operations for the three months ended March 31, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended March 31,		Period to Period Change
	2023	2022	
Net revenue	$ 70,650	$ 48,420	$ 22,230
Cost of goods sold	18,150	15,178	2,972
Gross profit	52,500	33,242	19,258
Gross Margin	*74.3 %*	*68.7 %*	
Operating expenses			
Research and development	8,056	11,236	(3,180)
General and administrative	12,168	10,013	2,155
Sales and marketing	42,654	33,063	9,591
Amortization of intangible assets	2,222	2,463	(241)
Acquisition-related costs	1,766	—	1,766
Total operating expenses	66,866	56,775	10,091
Loss from operations	(14,366)	(23,533)	9,167
Other income (expense)			
Interest and other income	3,628	43	3,585
Interest and other expense	683	(289)	972
Other income (expense), net	4,311	(246)	4,557
Loss before income tax benefit	(10,055)	(23,779)	13,724
Income tax benefit	(807)	(1,111)	304
Net loss	(9,248)	(22,668)	13,420
Foreign currency translation adjustment	3,071	(4,920)	7,991
Comprehensive loss	$ (6,177)	$ (27,588)	$ 21,411

Comparison of the Three Months Ended March 31, 2023 and 2022

Net Revenue

Net revenue was $70.7 million for the three months ended March 31, 2023, an increase of $22.2 million, or 45.9%, compared to $48.4 million for the three months ended March 31, 2022. Net revenue is primarily derived from the sale of our products to customers in the United States and certain international markets. The increase in net revenue is primarily due to increased sales of our products as we expanded our customer base in the U.S. and increased sales with our existing customer base. Our expanded product offering of the fourth-generation rechargeable SNM system in January 2023, recharge-free SNM system in March 2022 and the acquisition of the Bulkamid product in February 2021 have also contributed to our expansion of customers and more patients being treated with our existing customers.

Cost of Goods Sold and Gross Margin

We incurred $18.2 million of cost of goods sold for the three months ended March 31, 2023. We incurred $15.2 million of cost of goods sold for the three months ended March 31, 2022. Gross margin was 74.3% in the three months ended March 31, 2023, compared to 68.7% for the three months ended March 31, 2022. The increase in gross margin is primarily due to higher sales volumes and product mix, partially offset by increased inventory production costs related to our recharge-free SNM system following its commercial launch in March 2022.

Research and Development Expenses

Research and development expenses decreased $3.2 million, or 28.3%, to $8.1 million in the three months ended March 31, 2023, compared to $11.2 million in the three months ended March 31, 2022. The decrease in research and development expenses was primarily attributable to a decrease of $2.2 million in contract R&D and manufacturing costs following FDA approvals of the fourth-generation rechargeable SNM system in January 2023 and recharge-free SNM system in March 2022, and a decrease of $1.2 million in royalty expense due to lower net revenue derived from the AMF Licensed Products.

General and Administrative Expenses

General and administrative expenses increased $2.2 million, or 21.5%, to $12.2 million in the three months ended March 31, 2023, compared to $10.0 million in the three months ended March 31, 2022, primarily as a result of an increase of $2.0 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits.

Sales and Marketing Expenses

Sales and marketing expenses increased $9.6 million, or 29.0%, to $42.7 million in the three months ended March 31, 2023, compared to $33.1 million in the three months ended March 31, 2022. The increase in sales and marketing expenses was attributed to an increase of $7.7 million related to personnel costs including salaries, wages, sales personnel commissions, stock-based compensation and other employee-related benefits, an increase of $1.2 million related to facilities equipment, an increase of $1.1 million related to advertising expenses, partially offset by a decrease of $0.5 related to travel and expense fees.

Amortization of Intangible Assets

Amortization of intangible assets was $2.2 million in the three months ended March 31, 2023, compared to $2.5 million in the three months ended March 31, 2022. Amortization of intangible assets consisted primarily of technology and customer relationships acquired related to the Contura acquisition.

Acquisition-Related Costs

Acquisition-related costs were $1.8 million for the three months ended March 31, 2023 which related to the change in fair value of contingent consideration. There were no acquisition-related costs in the three months ended March 31, 2022.

Other Income (Expense), Net

Other income, net was $4.3 million in the three months ended March 31, 2023 consisting primarily of interest income on cash equivalents and short-term investments. Other expense, net was $0.2 million in the three months ended March 31, 2022 consisting primarily of losses on foreign currency transactions.

Income Tax Benefit

Income tax benefit was $0.8 million for the three months ended March 31, 2023 primarily related to losses in certain foreign jurisdictions. Income tax benefit was $1.1 million for the three months ended March 31, 2022 primarily related to losses in certain foreign jurisdictions.

Liquidity and Capital Resources

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

We incurred net losses of $9.2 million and $22.7 million for the three months ended March 31, 2023 and 2022, respectively, and had an accumulated deficit of $383.5 million as of March 31, 2023 compared to $374.3 million at December 31, 2022. We expect to continue to spend a significant amount of our existing resources on sales and marketing activities as we continue to commercialize and market our products in the United States and internationally.

As of March 31, 2023, we had cash, cash equivalents, and short-term investments of $357.1 million

compared to $357.2 million at December 31, 2022. We expect that our cash, cash equivalents, and short-term investments on hand will be sufficient to fund our operations through at least the next 12 months. We fund our operations through a combination of proceeds from public offerings of our common stock and cash receipts from sales of our products. As of March 31, 2023, we had no outstanding borrowings.

Beyond the next 12 months, our cash requirements will depend primarily on the amount of continued cash receipts from sales of our products, as well as our ability to develop or acquire new products, enter new markets, and compete effectively. We cannot accurately predict our long-term cash requirements at this time. We may need to raise additional financing in the future to facilitate our business operations. If we raise additional funds by issuing equity securities, our stockholders could experience dilution. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain additional financing when needed to satisfy our liquidity requirements, we may be required to scale back our operations.

Contractual Obligations and Cash Requirements

There have been no material changes to our contractual obligations or material cash requirements from those described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Cash Flows

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

	Three Months Ended March 31,	
	2023	**2022**
Net cash provided by (used in)		
Operating activities	$ (781)	$ (9,167)
Investing activities	694	(291)
Financing activities	1,930	1,444
Effect of exchange rate changes on cash and cash equivalents	(584)	316
Net increase (decrease) in cash and cash equivalents	$ 1,259	$ (7,698)

Net cash used in operating activities

Net cash used in operating activities was $0.8 million for the three months ended March 31, 2023 and consisted primarily of a net loss of $9.2 million and a decrease from changes in net operating assets of $5.7 million, partially offset by non-cash charges of $14.1 million. Net operating assets consisted primarily of inventory and accounts receivable due to the commercial growth in the United States. Non-cash charges consisted primarily of stock-based compensation.

Net cash used in operating activities was $9.2 million for the three months ended March 31, 2022 and consisted primarily of a net loss of $22.7 million, partially offset by non-cash charges of $8.9 million and an increase from changes in net operating assets of $4.6 million. Net operating assets consisted primarily of inventory and accounts receivable due to the commercial growth of our r-SNM System in the United States and the addition of Bulkamid sales. Non-cash charges consisted primarily of stock-based compensation and depreciation and amortization.

Net cash provided by (used in) investing activities

Net cash provided by investing activities was $0.7 million for the three months ended March 31, 2023 and consisted of sales and maturities of short-term investments, partially offset by purchases of short-term investments and property and equipment.

Net cash used in investing activities was $0.3 million for the three months ended March 31, 2022 and consisted of purchases of property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities was $1.9 million for the three months ended March 31, 2023 and consisted primarily of proceeds from exercise of stock options.

Net cash provided by financing activities was $1.4 million for the three months ended March 31, 2022 and consisted of proceeds from exercise of stock options.

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are described in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the SEC on March 1, 2023. 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 months ended March 31, 2023.

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 unaudited condensed consolidated financial statements or do not otherwise apply to our operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Risk

We had cash, cash equivalents, and short-term investments of $357.1 million as of March 31, 2023, which came from public offerings of our common stock and cash receipts from our product sales. The goals of our investment policy are liquidity and capital preservation and we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash, cash equivalents, and short-term investments. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Foreign Currency Exchange Rate Risk

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

Inflation Risk

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

Item 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 not effective as of March 31, 2023 due to the material weaknesses in internal control over financial reporting, as described below.

Material Weakness in Internal Control Over Financial Reporting

Management's assessment of our internal control over financial reporting as of December 31, 2022 identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We determined that a material weakness exists relating to the determination of the fair values of identifiable intangible assets and contingent consideration liability related to business combinations. This control deficiency creates a reasonable possibility that a material misstatement to the consolidated financial statements will not be prevented or detected on a timely basis.

In addition, during the three months ended September 30, 2022 management has determined that we have the following additional material weakness in its internal control over financial reporting:

We did not maintain appropriately designed information technology general controls in the areas of user access and segregation of duties related to certain information technology systems that support our financial reporting process, including certain controls within inventory and revenue. Additionally, certain manual controls within inventory and revenue that are dependent upon the information derived from the information technology systems are also determined to be ineffective.

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

Remediation Plan

We have identified steps, as further described below, to remediate the material weaknesses described in this Item 4 and to enhance our overall control environment. We are committed to ensuring that our internal controls over financial reporting are designed and operating effectively. Our remediation process includes, but is not limited to:

- Conducting a comprehensive review and assessment of internal controls over financial reporting to include the design of general information technology controls in the area of user access provisioning and monitoring controls to enforce appropriate system access and segregation of duties for systems supporting our internal controls processes and financial reporting, specifically related to revenue and inventory;

- Designing and implementing controls that address the completeness and accuracy of underlying data used in the performance of certain manual controls over accounting transactions and disclosures within revenue and inventory;
- Enhancing the design of controls, including the precision of the management review controls relating to key methodologies, assumptions and inputs used in the determination of the fair value of identifiable intangibles and a contingent consideration liability;
- Implementing a valuation review checklist that includes specific review attributes to ensure sufficient evidence of an effective review is documented and maintained to support management's conclusions; and
- Expanding personnel with appropriate experience to devote sufficient time and resources to our internal controls over fair value measurements.

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

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

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 March 31, 2023 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.

There have been no material developments in the litigation matters disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the SEC on March 1, 2023, during the quarter ended March 31, 2023.

Item 1A. Risk Factors.

You should carefully consider the information described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the SEC on March 1, 2023. There have been no material changes from the risk factors disclosed in our recent SEC filings, including our most recently filed Form 10-K, as referenced above.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

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

The information in Exhibits 32.1 and 32.2 shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Quarterly Report on Form 10-Q), unless the Company 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, INC.

Date: May 2, 2023 By: /s/ Raymond W. Cohen
Raymond W. Cohen
Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 2, 2023 By: /s/ Dan L. Dearen
Dan L. Dearen
President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

I, Raymond W. Cohen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 2, 2023

By: /s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer and Director

(Principal Executive Officer)

Exhibit 31.2

I, Dan L. Dearen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 2, 2023

By: /s/ Dan L. Dearen

Dan L. Dearen

President and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Axonics, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2023 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: May 2, 2023

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

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

Exhibit 32.2

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

In connection with the Quarterly Report of Axonics, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2023 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: May 2, 2023

By: /s/ Dan L. Dearen
Dan L. Dearen
President and Chief Financial Officer
(Principal Financial Officer)

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