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

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**FORM 10-Q**

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- (Mark One)
- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2021  
or  
 **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38721

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**Axonics, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**26 Technology Drive**  
**Irvine, California**  
(Address of principal executive  
offices)

**45-4744083**  
(I.R.S. Employer  
Identification Number)

**92618**  
(Zip Code)

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

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

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

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

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

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

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

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

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

As of November 2, 2021, 46,297,344 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;
  - introductions and announcements of new technologies by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
  - successful integration of acquired operations into our ongoing business;
  - announcements of regulatory approval or disapproval of our products and any future enhancements to our products;
  - adverse results from or delays in clinical studies of our products;
  - variations in our financial results or those of companies that are perceived to be similar to us;
  - success or failure of competitive products or therapies in the markets in which we do business;
  - changes in the structure of healthcare payment of our products;
  - announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
  - economic and market conditions in general and in the medical technology industry, specifically, including the size and growth, if any, of the market, and issuance of securities analysts’ reports or recommendations;
  - rumors and market speculation involving us or other companies in our industry;
  - sales of substantial amounts of our stock by directors, officers or significant stockholders, or the expectation that such sales might occur;
  - additions or departures of key personnel;
  - changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
  - the continued impact of the novel coronavirus (COVID-19) pandemic, and the related responses of the government and consumers on our business, financial condition and results of operations.
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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, r-SNM®, Axonics SNM System® 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.

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**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)

	September 30, 2021	December 31, 2020
	(unaudited)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 228,797	\$ 241,181
Accounts receivable, net of allowance for doubtful accounts of \$385 and \$465 at September 30, 2021 and December 31, 2020, respectively	26,641	18,270
Inventory, net	70,358	63,060
Prepaid expenses and other current assets	4,433	5,435
<b>Total current assets</b>	<b>330,229</b>	<b>327,946</b>
Property and equipment, net	6,168	6,328
Intangible assets, net	108,302	196
Other assets	7,041	7,736
Goodwill	109,565	—
<b>Total assets</b>	<b>\$ 561,305</b>	<b>\$ 342,206</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 10,512	\$ 10,660
Accrued liabilities	6,424	6,684
Accrued compensation and benefits	9,305	5,948
Operating lease liability, current portion	1,401	1,280
Debt, net of unamortized debt issuance costs, current portion	109	21,110
<b>Total current liabilities</b>	<b>27,751</b>	<b>45,682</b>
Operating lease liability, net of current portion	8,152	9,154
Deferred tax liabilities, net	26,432	—
Other long-term liabilities	8,880	—
<b>Total liabilities</b>	<b>71,215</b>	<b>54,836</b>
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at September 30, 2021 and December 31, 2020; 46,258,758 and 39,931,030 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	5	4
Additional paid-in capital	796,397	522,296
Accumulated deficit	(299,400)	(234,499)
Accumulated other comprehensive loss	(6,912)	(431)
<b>Total stockholders' equity</b>	<b>490,090</b>	<b>287,370</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 561,305</b>	<b>\$ 342,206</b>

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net revenue	\$ 46,913	\$ 35,243	\$ 127,155	\$ 76,752
Cost of goods sold	15,719	13,434	46,828	31,792
Gross profit	31,194	21,809	80,327	44,960
Operating Expenses				
Research and development	8,648	7,719	27,115	20,944
General and administrative	8,720	5,773	23,381	18,963
Sales and marketing	28,112	17,057	74,451	47,846
Amortization of intangible assets	2,216	29	5,094	86
Acquisition-related costs	—	—	4,414	—
Total operating expenses	47,696	30,578	134,455	87,839
Loss from operations	(16,502)	(8,769)	(54,128)	(42,879)
Other Expense				
Interest income	9	35	24	742
Interest and other expense	(229)	(434)	(7,528)	(1,429)
Other expense, net	(220)	(399)	(7,504)	(687)
Loss before income tax expense	(16,722)	(9,168)	(61,632)	(43,566)
Income tax expense	528	—	3,269	1
Net loss	(17,250)	(9,168)	(64,901)	(43,567)
Foreign currency translation adjustment	(5,138)	99	(6,481)	(186)
Comprehensive loss	\$ (22,388)	\$ (9,069)	\$ (71,382)	\$ (43,753)
Net loss per share, basic and diluted (see Note 1)	\$ (0.38)	\$ (0.24)	\$ (1.53)	\$ (1.20)
Weighted-average shares used to compute basic and diluted net loss per share (see Note 1)	44,848,023	38,830,924	42,436,061	36,312,984

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 Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance at December 31, 2020	39,931,030	\$ 4	\$ 522,296	\$ (234,499)	\$ (431)	\$ 287,370
Issuance of common stock for employee stock option exercises for cash	206,507	—	2,821	—	—	2,821
Restricted Shares Award (RSA) issuances and forfeitures for terminations, net and stock-based compensation	358,300	—	3,809	—	—	3,809
Issuance of common stock for vesting of Restricted Stock Units (RSU) and stock-based compensation	169,054	—	1,494	—	—	1,494
Issuance of common stock for acquisition of Contura Limited	1,096,583	—	55,728	—	—	55,728
Issuance of common stock for exclusive license asset	65,594	—	3,637	—	—	3,637
Foreign currency translation adjustment	—	—	—	—	(2,202)	(2,202)
Net loss	—	—	—	(22,503)	—	(22,503)
Balance at March 31, 2021	41,827,068	4	589,785	(257,002)	(2,633)	330,154
Issuance of common stock for employee stock option exercises for cash	206,921	—	2,095	—	—	2,095
RSA issuances and forfeitures for terminations, net and stock-based compensation	31,975	—	4,381	—	—	4,381
Issuance of common stock for vesting of RSU and stock-based compensation	—	—	1,946	—	—	1,946
Follow-on offering - issuance of 4,025,000 shares at \$50.00 per share, less closing costs of \$11,272	4,025,000	1	189,977	—	—	189,978
Foreign currency translation adjustment	—	—	—	—	859	859
Net loss	—	—	—	(25,148)	—	(25,148)
Balance at June 30, 2021	46,090,964	5	788,184	(282,150)	(1,774)	504,265
Issuance of common stock for employee stock option exercises for cash	86,894	—	1,523	—	—	1,523
RSA issuances and forfeitures for terminations, net and stock-based compensation	80,900	—	4,723	—	—	4,723
Issuance of common stock for vesting of RSU and stock-based compensation	—	—	1,967	—	—	1,967
Foreign currency translation adjustment	—	—	—	—	(5,138)	(5,138)
Net loss	—	—	—	(17,250)	—	(17,250)
Balance at September 30, 2021	46,258,758	5	796,397	(299,400)	(6,912)	490,090

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance at December 31, 2019	34,110,995	\$ 3	\$ 363,012	\$ (179,584)	\$ (428)	\$ 183,003
Issuance of common stock for employee stock option exercises for cash	181,456	—	344	—	—	344
RSA issuances and forfeitures for terminations, net and stock-based compensation	171,875	—	3,039	—	—	3,039
Issuance of common stock for vesting of RSU and stock-based compensation	46,336	—	883	—	—	883
Foreign currency translation adjustment	—	—	—	—	(177)	(177)
Net loss	—	—	—	(14,616)	—	(14,616)
Balance at March 31, 2020	34,510,662	3	367,278	(194,200)	(605)	172,476
Issuance of common stock for employee stock option exercises for cash	319,680	—	1,008	—	—	1,008
RSA issuances and forfeitures for terminations, net and stock-based compensation	32,063	—	2,969	—	—	2,969
Issuance of common stock for vesting of RSU and stock-based compensation	—	—	847	—	—	847
Follow-on offering - issuance of 4,600,000 shares at \$32.50 per share, less closing costs of \$9,013	4,600,000	1	140,486	—	—	140,487
Foreign currency translation adjustment	—	—	—	—	(108)	(108)
Net loss	—	—	—	(19,783)	—	(19,783)
Balance at June 30, 2020	39,462,405	4	512,588	(213,983)	(713)	297,896
Issuance of common stock for employee stock option exercises for cash	164,233	—	1,296	—	—	1,296
RSA issuances and forfeitures for terminations, net and stock-based compensation	127,000	—	2,920	—	—	2,920
Issuance of common stock for vesting of RSU and stock-based compensation	—	—	855	—	—	855
Foreign currency translation adjustment	—	—	—	—	99	99
Net loss	—	—	—	(9,168)	—	(9,168)
Balance at September 30, 2020	39,753,638	4	517,659	(223,151)	(614)	293,898

See accompanying notes to unaudited condensed consolidated financial statements.



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

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (64,901)	\$ (43,567)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	6,483	1,253
Stock-based compensation	18,320	11,513
Amortization of debt issuance costs	4,991	594
Provision for doubtful accounts	(92)	390
Deferred income taxes and other items, net	4,961	142
Changes in operating assets and liabilities, net of business acquisition		
Accounts receivable	(6,669)	(10,161)
Inventory	(6,671)	(28,600)
Prepaid expenses and other current assets	1,075	1,352
Other assets	(273)	16
Accounts payable	62	3,533
Accrued liabilities	(978)	3,508
Accrued compensation and benefits	3,047	4,141
Lease liability	115	458
Net cash used in operating activities	<u>(40,530)</u>	<u>(55,428)</u>
<b>Cash Flows from Investing Activities</b>		
Purchases of property and equipment	(1,177)	(1,915)
Acquisition of a business, net of cash acquired	(140,741)	—
Proceeds from sales and maturities of short-term investments	—	12,592
Net cash (used in) provided by investing activities	<u>(141,918)</u>	<u>10,677</u>
<b>Cash Flows from Financing Activities</b>		
Payment of debt issuance costs	(106)	—
Proceeds from debt	75,000	—
Repayment of debt	(101,000)	—
Proceeds from issuance of common stock upon follow-on public offering	201,250	149,500
Payment of common stock issuance costs upon follow-on public offering	(11,272)	(9,013)
Proceeds from exercise of stock options	6,439	2,648
Net cash provided by financing activities	<u>170,311</u>	<u>143,135</u>
Effect of exchange rate changes on cash and cash equivalents	(247)	(186)
Net (decrease) increase in cash and cash equivalents	<u>(12,384)</u>	<u>98,198</u>
Cash and cash equivalents, beginning of year	241,181	171,082
Cash and cash equivalents, end of period	<u>\$ 228,797</u>	<u>\$ 269,280</u>
<b>Supplemental Disclosure of Cash Flow Information</b>		
Cash paid for interest	\$ 2,178	\$ 849
Cash paid for taxes	\$ 1	\$ —
<b>Noncash Investing and Financing Activities</b>		
Common stock issuance for business acquisition	\$ 55,728	\$ —
Contingent consideration for business acquisition	\$ 7,630	\$ —
Common stock issuance for exclusive license asset	\$ 3,637	\$ —
Accrued loan fees as debt issuance costs	\$ 4,500	\$ —

See accompanying notes to 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. In August 2013, the Company changed its name to Axonics Modulation Technologies, Inc. In March 2021, the Company changed its name to Axonics, Inc. The Company had no operations until October 1, 2013, when the license agreement between Alfred E. Mann Foundation for Scientific Research (AMF) and the Company (the License Agreement) was entered into. The Company is a medical technology company that develops and commercializes innovative and minimally invasive products to treat urinary and fecal dysfunction. The Company has designed and developed the rechargeable sacral neuromodulation (SNM) system (r-SNM System), which delivers mild electrical pulses to the targeted sacral nerve in order to restore normal communication to and from the brain to reduce the symptoms of overactive bladder (OAB), urinary retention (UR) and fecal incontinence (FI). The r-SNM System is protected by intellectual property based on Company-generated innovations and patents and other intellectual property licensed from AMF. The Company has marketing approvals in the United States, Europe, Canada, and Australia for all relevant clinical indications. The premarket approval (PMA) application for the r-SNM System for the treatment of FI was approved by the U.S. Food and Drug Administration (FDA) on September 6, 2019, and the PMA application for the r-SNM System for the treatment of OAB and UR was approved by the FDA on November 13, 2019. Accordingly, the Company began U.S. commercialization of its r-SNM System in the fourth quarter of 2019. Prior to the fourth quarter of 2019, the Company derived revenue only from its international operations in select markets including England, the Netherlands and Canada, and its activities have consisted primarily of developing the r-SNM System, conducting its RELAX-OAB post-market clinical follow-up study in Europe, its ARTISAN-SNM pivotal clinical study in the United States and hiring and training its U.S. commercial team in preparation for the launch of the r-SNM System in the United States. Beginning in February 2021 with the acquisition of Contura Limited, the Company also markets Bulkamid, a urethral bulking agent to treat female stress urinary incontinence (SUI). For more information, see Note 8.

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

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

***May 2021 Follow-On Offering***

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

***Principles of Consolidation***

The accompanying 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, and Axonics GmbH. Intercompany accounts and transactions have been eliminated in consolidation.

***Basis of Presentation******Interim Financial Statements***

The interim condensed consolidated financial statements and related footnote disclosures as of and for the three and nine months ended September 30, 2021 are unaudited, and are not necessarily indicative of the Company's operating results for a full year. The unaudited interim condensed consolidated financial statements

include all normal and recurring adjustments necessary for a fair presentation of the Company's financial results for the three and nine months ended September 30, 2021 in accordance with United States (U.S.) generally accepted accounting principles (GAAP), however, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the U.S. Securities and Exchange Commission (SEC) rules and regulations relating to interim financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included within the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (filed with the SEC on March 1, 2021).

#### *Reclassifications*

Certain prior period reported amounts have been reclassified to conform with the current period presentation.

#### **COVID-19**

The recent COVID-19 outbreak, and the resulting restrictions intended to slow the spread of COVID-19, including stay-at-home orders, business shutdowns and other restrictions, has adversely affected the Company's business in several ways. The primary impact on the Company's business was the cancellation or delay of elective procedures in certain areas to allow health care facilities to prioritize the treatment of COVID-19 patients during the initial stages and resurgence periods of the pandemic or because patients are avoiding health care facilities that they feel are unsafe. These developments materially reduced the number of procedures using the Company's r-SNM System. If governmental authorities recommend that it is deemed advisable for health care facilities to not perform outpatient elective procedures as was the case in late March and April of 2020 and again in the third quarter of 2021 related to the Delta variant, the Company expects it would materially harm the Company's revenues and potentially increase the Company's operating loss. Even as efforts to contain the pandemic have made progress and some restrictions have relaxed, new variants of the virus may continue to cause additional outbreaks. These challenges will likely continue for the duration of the pandemic and could reduce our revenue and negatively impact our business, financial condition and results of operations while the pandemic continues. If these delays in procedures occur in the future, the Company may have to scale back its business, including reducing headcount, which could have a negative impact on the Company's long-term operations. The Company could also experience other negative impacts of the COVID-19 outbreak such as the lack of availability of the Company's key personnel, temporary closures of the Company's office or the facilities of the Company's business partners, customers, third party service providers or other vendors, and the interruption of the Company's supply chain, distribution channels, liquidity and capital or financial markets.

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

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

#### **Use of Estimates**

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

**Revenue Recognition**

Revenue recognized during the three and nine months ended September 30, 2021 and 2020 relates entirely to the sale of the Company's products to its customers and distributors.

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

In accordance with Company policy and based on the Company's historical experience, the allowance for product returns was \$0.2 million and \$0.3 million at September 30, 2021 and December 31, 2020, respectively. Damaged or defective products are replaced at no charge under the Company's standard warranty. For the three and nine months ended September 30, 2021, the replacement costs were minimal and \$0.2 million, respectively. For the three and nine months ended September 30, 2020, replacement costs were minimal 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 and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>SNM net revenue</b>				
United States	\$ 39,147	\$ 34,139	\$ 110,135	\$ 73,833
International markets	922	1,104	3,031	2,919
	\$ 40,069	\$ 35,243	\$ 113,166	\$ 76,752
<b>Bulkamid net revenue</b>				
United States	\$ 3,921	\$ —	\$ 6,870	\$ —
International markets	2,923	—	7,119	—
	\$ 6,844	\$ —	\$ 13,989	\$ —
<b>Total net revenue</b>	<b>\$ 46,913</b>	<b>\$ 35,243</b>	<b>\$ 127,155</b>	<b>\$ 76,752</b>

**Allowance for Doubtful Accounts**

The Company makes estimates of the collectability of accounts receivable in accordance with ASU 2016-13. The Company's estimate of future losses is made by management based upon historical bad debts, customer receivable balances, age of customer receivable balances, customers' financial conditions and reasonable forecasted economic trends. Despite the Company's efforts to minimize credit risk exposure, customers could be adversely affected if future economic and industry trends, including those related to COVID-19, change in such a

manner as to negatively impact their cash flows. The full effects of COVID-19 on the Company's customers are highly uncertain and cannot be predicted. As a result, the Company's future collection experience can differ significantly from historical collection trends. If the Company's customers experience a negative impact on their cash flows, it could have a material adverse effect on the Company's results of operations and financial condition.

The following table summarizes the changes in our allowance for doubtful accounts (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Balance at beginning of period	\$ 465	\$ 75
Write-offs	12	—
Bad debt expense, net	(92)	390
Balance at end of period	<u>\$ 385</u>	<u>\$ 465</u>

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

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

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

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

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

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

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

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

assumptions is obtained and any change in fair value of the contingent consideration is recorded in the consolidated statements of comprehensive loss. Significant increases or decreases in any of those inputs in isolation would result in a significantly lower or higher fair value measurement. Generally, a change in the assumption used for the projected revenues would result in a directionally similar change to the overall estimate of the contingent consideration. The fair value of contingent consideration of \$8.9 million at September 30, 2021 is reflected in other long-term liabilities on the Company's condensed consolidated balance sheets with the change in fair value of \$1.3 million during the three months ended September 30, 2021 reflected in general and administrative expenses in the consolidated statements of comprehensive loss.

The following table summarizes the changes in the fair value of recurring Level 3 fair value measurements during the nine months ended September 30, 2021 (in thousands):

Liabilities	
Contingent consideration:	
December 31, 2020	\$ —
February 25, 2021 Acquisition	7,630
Loss on change in fair value included in earnings	1,250
September 30, 2021	<u>\$ 8,880</u>

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

### **Investment Securities**

Those investments in debt securities with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments in debt securities with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based on the fair value hierarchy (Level 1 and Level 2 inputs in the fair value hierarchy), and consists primarily of commercial paper, corporate notes and U.S. government and agency securities. Unrealized gains or losses, deemed temporary in nature, are reported as other comprehensive income within the condensed consolidated statement of comprehensive income (loss). There were no unrealized gains or losses during the three and nine months ended September 30, 2021 and 2020.

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

The Company had no outstanding investment securities as of September 30, 2021 and December 31, 2020.

### **Foreign Currency Translation**

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Revenue and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' equity in accumulated other comprehensive gain or loss until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss). As of September 30, 2021 and December 31, 2020, all foreign currency translation gains (losses) have been unrealized and included in accumulated other comprehensive loss. Accumulated other comprehensive loss consists entirely of losses or gains from translation of foreign subsidiaries at September 30, 2021 and December 31, 2020.

### ***Inventory, Net***

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

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

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

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

The Company analyzes inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its net realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of the r-SNM System is subject to strict quality control, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to the Company's inventory values. The Company also applies judgment related to the results of quality tests that are performed throughout the production process, as well as the understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre- and post-production processes, and the Company continually gathers information regarding product quality for periods after the manufacturing date. The Company's products currently have a maximum estimated shelf life range of 12 to 36 months and, based on sales forecasts, the Company expects to realize the carrying value of the product inventory. In the future, reduced demand, quality issues, or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

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

As of September 30, 2021, the Company had \$45.3 million, \$9.6 million and \$15.5 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively, net of reserves of \$0.3 million. As of December 31, 2020, the Company had \$42.1 million, \$3.5 million and \$17.5 million of finished goods inventory, work-in-process inventory and raw materials inventory, respectively. Reserves were de minimus as of December 31, 2020.

### ***Customer and Vendor Concentration***

As of September 30, 2021 and December 31, 2020, there were no customers who accounted for over 10% of the Company's consolidated accounts receivable. As of September 30, 2021 and December 31, 2020, there was one and one vendor, respectively, who accounted for over 10% of the Company's consolidated accounts payable.

### **Property and Equipment**

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

### **Goodwill**

Goodwill represents the excess purchase price over the fair values of the identifiable assets acquired less the liabilities assumed. Goodwill is tested for impairment at least annually. 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 performs an annual impairment test for goodwill in the fourth quarter of each year. The Company considers qualitative indicators of the fair value of a reporting unit when it is unlikely that a reporting unit has impaired goodwill. During the nine months ended September 30, 2021, the Company did not record any impairment charges related to goodwill.

### **Intangible Assets**

#### **Patent license asset**

The intangible asset represents exclusive rights to an additional field-of-use on the patent suite within the License Agreement with AMF. The additional field-of-use was provided in exchange for 50,000 shares of Series A preferred stock, the fair value of which was \$1.0 million in 2013. The intangible asset was recorded at its fair value of \$1.0 million at the date contributed. In connection with the IPO, such shares of Series A preferred stock were converted into common stock. Amortization of this asset is recorded over the shorter of the patent or legal life on a straight-line basis. The weighted-average amortization period is 8.71 years. Accumulated amortization of this intangible asset is \$0.9 million and \$0.8 million at September 30, 2021 and December 31, 2020, respectively. The amortization of this intangible asset was \$0.1 million during the nine months ended September 30, 2021 and 2020. The amortization of this intangible asset was minimal during the three months ended September 30, 2021 and 2020. 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 9.

#### **Exclusive license asset**

The intangible asset represents exclusive rights of existing technologies and development services from MST entered into on March 2, 2021. The agreement was provided in exchange for 65,594 shares of common stock, \$0.0001 par value, the fair value of which was \$3.6 million upon transfer. The intangible asset was recorded at its fair value of \$3.3 million at the date of the agreement, with the difference of \$0.3 million recorded as a vendor credit in accounts payable in the condensed consolidated balance sheets. Amortization of this asset is recorded over the four-year term of the agreement on a straight-line basis. There was \$0.2 million and \$0.4 million amortization of this intangible asset recorded during the three and nine months ended September 30, 2021, respectively. 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 9.

#### **Contura acquisition**

The intangible assets represent technology, trade names and trademarks, and customer relationships acquired from Contura on February 25, 2021. For additional information, see Notes 8 and 9.

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

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



### **Leases**

In accordance with 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. The aforementioned bright lines are applied consistently to the Company’s entire portfolio of leases.

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

### **Research and Development**

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

### **Advertising Expense**

The Company expenses advertising costs as they are incurred. During the three and nine months ended September 30, 2021, advertising expense totaled \$2.6 million and \$5.5 million, respectively, and are recorded within the sales and marketing expenses in its consolidated statements of comprehensive loss. During the three and nine months ended September 30, 2020, advertising expense totaled \$0.8 million and \$1.4 million, respectively, and are recorded within the sales and marketing expenses in its consolidated statements of comprehensive loss.

### **Income Taxes**

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

### ***Stock-Based Compensation***

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

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

The Company also grants shares of performance-based restricted stock units that typically vest after one year only if the Company has also achieved certain performance objectives as defined and approved by the Company's board of directors. The fair value of performance awards are determined based on the Company's stock price at the date of grant and expensed over the performance period based on the probability of achieving the performance objectives. In addition, the Company also grants market-based restricted stock units that have combined market conditions and service conditions for vesting, for which the Company uses the Monte Carlo valuation model to value equity awards (as of the date of grant).

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

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

For the three and nine months ended September 30, 2021, there were 2,459,912 and 2,460,176 potentially dilutive weighted-average shares, respectively, that were not included in the computation of diluted weighted-average shares of common stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss. For the three and nine months ended September 30, 2020, there were 2,279,353 and 2,251,155 potentially dilutive weighted-average shares, respectively, that were not included in the computation of diluted weighted-average shares of common stock and common stock equivalent shares outstanding because their effect would have been antidilutive given the Company's net loss.

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

In December 2019, the FASB issued ASU 2019-12, "Income Taxes—Simplifying the Accounting for Income Taxes," which simplifies the accounting for income taxes by clarifying and amending existing guidance related to the recognition of franchise tax, the evaluation of a step-up in the tax basis of goodwill and the effects of enacted changes in tax laws or rates in the effective tax rate computation, among other clarifications. This guidance is effective for annual periods beginning after December 15, 2020, which was the Company's first quarter of fiscal year 2021, with early adoption permitted. The adoption of this guidance did not have an impact on the Company's consolidated financial statements or related disclosures.

**Note 2. Property and Equipment**

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

	September 30, 2021	December 31, 2020
Research and development equipment	\$ 1,484	\$ 1,205
Computer hardware and software	2,468	2,286
Tools and molds	1,597	1,404
Leasehold improvements	3,772	3,759
Furniture and fixtures	1,514	1,360
Construction in progress	537	129
	<u>11,372</u>	<u>10,143</u>
Less: accumulated depreciation and amortization	(5,204)	(3,815)
	<u>\$ 6,168</u>	<u>\$ 6,328</u>

Depreciation and amortization expense of property and equipment was \$0.5 million and \$1.4 million for the three and nine months ended September 30, 2021, respectively. Depreciation and amortization expense of property and equipment was \$0.5 million and \$1.2 million for the three and nine months ended September 30, 2020, respectively.

**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 and in September 2020, the lease was amended to extend the expiration date to July 31, 2022. Upon the execution of the amendments, which were deemed to be a lease modification, the Company reassessed the lease liability using the discount rate at the modification date and recorded ROU assets for the same amount. The Company also reassessed the lease classification and concluded that the lease continues to be an operating lease. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-line basis over the expected lease term.

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

In June 2019, the Company entered into an eight-year operating lease for approximately 32,621 square feet of office space beginning on January 15, 2020 and expiring on January 31, 2028. The Company uses these premises as its new principal executive offices and for general office space. The Company intends to utilize its other currently-leased spaces through the lease expiration dates to conduct the training of its sales team and for manufacturing purposes. Under the terms of the lease, the Company is responsible for taxes, insurance, and maintenance expense. The lease contains certain scheduled rent increases. Rent expense is recognized on a straight-

line basis over the expected lease term. The Company has a renewal option to extend the term of the lease for a period of five years beyond the initial term. Under the terms of the lease, the base rent payable with respect to each renewal term will be equal to the prevailing market rental rent as of the commencement of the applicable renewal term. In the event of a default of certain of the Company's obligations under the lease, the Company's landlord would have the right to terminate the lease.

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

During the three and nine months ended September 30, 2021, ROU assets obtained in exchange for new operating lease liabilities were none and \$0.1 million, respectively. During the three and nine months ended September 30, 2020, ROU assets obtained in exchange for new operating lease liabilities were none and \$3.0 million, respectively. As of September 30, 2021 and December 31, 2020, the ROU asset has a balance of \$6.4 million and \$7.1 million, respectively. The operating lease ROU asset is included within the Company's other non-current assets, and lease liabilities are included in current or noncurrent liabilities on the Company's condensed consolidated balance sheets. During the three and nine months ended September 30, 2021, cash paid for amounts included in operating lease liabilities were \$0.5 million and \$1.5 million, respectively. During the three and nine months ended September 30, 2020, cash paid for amounts included in operating lease liabilities were \$0.4 million and \$1.0 million, respectively. Amortization of the ROU asset was \$0.3 million and \$0.8 million for the three and nine months ended September 30, 2021. Amortization of the ROU asset was \$0.2 million and \$0.6 million for the three and nine months ended September 30, 2020, respectively.

As of September 30, 2021 and December 31, 2020, the weighted-average remaining lease term for the Company's operating leases were 6.0 years and 6.6 years, respectively. The weighted-average discount rate used to determine the present value of the Company's operating leases' future payments was 6.7% as of September 30, 2021 and December 31, 2020.

Total lease cost for the three and nine months ended September 30, 2021 and 2020 are as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Lease cost				
Operating lease cost	\$ 524	\$ 491	\$ 1,583	\$ 1,472
Short-term lease cost	25	51	77	119
Variable lease cost	54	65	152	123
<b>Total lease cost</b>	<b>\$ 603</b>	<b>\$ 607</b>	<b>\$ 1,812</b>	<b>\$ 1,714</b>

#### ***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 will automatically increase each year after 2018, subject to a maximum amount of \$200,000 per year. The Company generated net SNM revenue of \$40.1 million and \$113.2 million during the three and nine

months ended September 30, 2021, respectively, and recorded related royalties of \$1.6 million and \$4.5 million during the three and nine months ended September 30, 2021, respectively. The Company generated net SNM revenue of \$35.2 million and \$76.8 million during the three and nine months ended September 30, 2020, respectively, and recorded related royalties of \$1.4 million and \$3.0 million during the three and nine months ended September 30, 2020, respectively. Royalty expense is included in operating expenses in the condensed consolidated statements of comprehensive loss. Accrued royalty of \$1.6 million and \$1.4 million as of September 30, 2021 and December 31, 2020, respectively, is included within accrued liabilities on the Company's condensed consolidated balance sheets.

#### **Legal Matters**

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

On March 16, 2020, the Company filed seven petitions before the United States Patent and Trademark Office (USPTO) requesting inter partes review (IPR) to contest the validity of each of the Medtronic patents that Medtronic has alleged are being infringed by the Company. In September 2020, the USPTO decided that it will accept or "institute" the IPR process for six of the seven patents, finding that the Company had demonstrated a reasonable likelihood that at least one, if not all, of the claims of these six patents are invalid. The USPTO issued decisions on the IPR petitions in September 2021. The USPTO invalidated several claims in the Medtronic patents but declined to invalidate the majority of asserted claims. The Company plans to appeal the decisions on the claims that were not invalidated. Following these IPR decisions, the judge presiding over the litigation in the United States District Court for the Central District of California lifted the stay on litigation proceedings.

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. Long-Term Debt**

In June 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to the term loan under the Loan and Security Agreement with Silicon Valley Bank entered into in February 2021, were paid in full. The unamortized debt issuance costs of \$4.4 million as of March 31, 2021 was expensed and recognized as interest expense during the three months ended June 30, 2021.

In January 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to the term loan under the Loan and Security Agreement with Silicon Valley Bank entered into in February 2018, were paid in full. The unamortized debt issuance costs of \$0.4 million as of December 31, 2020 was expensed and recognized as interest expense during the three months ended March 31, 2021.

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

	September 30, 2021	December 31, 2020
Debt, principal	\$ 109	\$ 20,000
Accrued loan fees	—	1,500
Debt, total	109	21,500
Less: unamortized debt issuance costs	—	(390)
Debt, net of unamortized debt issuance costs	\$ 109	\$ 21,110

#### Note 5. Stock-based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 1,549	\$ 882	\$ 4,435	\$ 2,493
General and administrative	2,158	1,448	5,930	4,726
Sales and marketing	2,983	1,445	7,955	4,294
	\$ 6,690	\$ 3,775	\$ 18,320	\$ 11,513

#### Stock Option Activity

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Expected term (in years)	5.50	—	5.46 - 6.00	6.05
Stock volatility	63.49%	—	63.49%	72.01%
Risk-free interest rate	0.85%	—	0.53% - 1.16%	1.37%
Dividend rate	—	—	—	—

The Company used the simplified method of determining the expected term of stock options as the Company believes this represents the best estimate of the expected term of a new option. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have sufficient trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments, whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The assumptions regarding the expected term of the options and the expected volatility of the stock price are subjective, and these assumptions have a significant effect on the estimated fair value amounts. The weighted-average grant date fair value of options granted was \$33.08 and \$32.93 for the three and nine months ended September 30, 2021, respectively. The weighted-average grant date fair value of options granted was none and \$18.56 for the three and nine months ended September 30, 2020, respectively.

As of September 30, 2021 and December 31, 2020, there was \$8.4 million and \$11.6 million, respectively, of total unrecognized compensation cost related to unvested stock options that is expected to be recognized over a weighted-average period of approximately 1.8 years and 2.4 years, respectively.

The following table summarizes stock option activity for the nine months ended September 30, 2021 under the 2014 and 2018 Plans (in thousands, except share and per share data):

	<b>Number of Options</b>	<b>Weighted-Average Exercise Price Per Share</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2020	1,955,243	\$ 16.01	
Options granted	46,000	58.07	
Options exercised	(500,322)	12.53	\$ 23,450 (1)
Options forfeited	(36,957)	24.18	
Outstanding at September 30, 2021	<u>1,463,964</u>	<u>\$ 18.32</u>	<u>\$ 68,475 (2)</u>

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

(2) Represents the total difference between the Company's closing stock price on the last trading day of the third quarter of 2021 and the stock option exercise price, multiplied by the number of in-the-money options as of September 30, 2021. The amount of intrinsic value will change based on the fair market value of the Company's stock.

The weighted-average remaining contractual term of options outstanding and exercisable is 7.2 years and 7.7 years at September 30, 2021 and December 31, 2020, respectively.

#### ***Restricted Shares Awards Activity***

As of September 30, 2021 and December 31, 2020, there was \$42.3 million and \$22.6 million, respectively, of total unrecognized compensation cost related to unvested restricted shares awards that is expected to be recognized over a weighted-average period of approximately 3.2 years and 3.3 years, respectively.

The following table summarizes restricted shares awards activity for the nine months ended September 30, 2021:

	Number of Restricted Shares Awards	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2020	817,183	\$ 31.70
Restricted shares awards granted	552,400	56.95
Restricted shares awards vested	(175,372)	29.35
Restricted shares awards forfeited	(81,225)	36.53
Outstanding at September 30, 2021	1,112,986	\$ 44.25

#### **Restricted Stock Units Activity**

As of September 30, 2021 and December 31, 2020, there was \$3.9 million and \$1.2 million, respectively, of total unrecognized compensation cost related to unvested restricted stock units that is expected to be recognized over a weighted-average period of approximately 0.8 years and 0.9 years, respectively.

The following table summarizes restricted stock units activity for the nine months ended September 30, 2021:

	Number of Restricted Stock Units	Weighted-Average Fair Value Per Share at Grant Date
Outstanding at December 31, 2020	207,101	\$ 23.49
Restricted stock units granted	212,417	43.62
Restricted stock units vested	(169,054)	19.89
Outstanding at September 30, 2021	250,464	\$ 42.99

#### **Note 6. Income Taxes**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Provision for income taxes	\$528	\$—	\$3,269	\$1
Effective tax rate	3.16%	—%	5.30%	—%

The Company accounts for income taxes according to ASC 740, which, among other things, requires the estimation of the annual effective income tax rate for the full year applied to year-to-date ordinary income (loss) to compute the year-to-date tax expense (benefit). 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 piece weighted based on its reliability. As of September 30, 2021, the Company continues to maintain a full valuation allowance against its U.S. net deferred tax assets.



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 nine months ended September 30, 2021 was primarily the result of remeasuring deferred tax liabilities in the Company's U.K. jurisdiction due to the increase in the U.K. income tax rate from 19% to 25% which was enacted during Q2 2021 and effective April 1, 2023.

At December 31, 2020, the Company had federal and California net operating loss (NOL) carryforwards of approximately \$213.5 million. Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code), use of the Company's NOL carryforwards may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a rolling three-year period. The Company 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. Future ownership changes could impact the Company's ability to utilize NOL carryforwards. The Company has recorded a full valuation allowance against its otherwise recognizable U.S. deferred income tax assets as of December 31, 2020. The Company has determined, after evaluating all positive and negative historical and prospective evidence, that it is more likely than not that the U.S. deferred income tax assets will not be realized. Ownership changes could impact the Company's ability to utilize NOL carryforwards remaining at an ownership change date. The Company's NOL carryforwards were generated from domestic operations. The federal NOLs from the 2013-2017 tax years will expire between 2033 and 2037 and NOLs from 2018-2020 will carryover indefinitely. The state NOLs will expire between 2033 and 2039. Under California Assembly Bill 85, effective June 29, 2020, net operating loss deductions were suspended for tax years beginning in 2020, 2021, and 2022 and the carry forward periods of any net operating losses not utilized due to such suspension were extended.

#### **CARES Act**

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

#### **Note 7. Employee Benefit Plan**

The Company sponsors a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pre- or post-tax basis. Contributions to the plan by the Company may be made at the discretion of the board of directors. During the three and nine months ended September 30, 2021, the Company contributions to the plan amounted to \$0.4 million and \$1.4 million, respectively. During the three and nine months ended September 30, 2020, the Company contributions to the plan amounted to \$0.4 million and \$1.2 million, respectively.

#### **Note 8. Acquisition**

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

The Company accounted for the acquisition as a business combination pursuant to ASC 805. In accordance with ASC 805, fair values are assigned to tangible and identifiable intangible assets acquired and liabilities assumed at the acquisition date based on the information that was available as of the acquisition date. The Company believes that the information available provides a reasonable basis for estimating the fair values of assets acquired and liabilities assumed for the acquisition, however, preliminary measurements of fair value, including, but not limited to, contingent consideration, intangible assets, goodwill, and deferred taxes, are subject to change during the measurement period, and such changes could be material. The Company expects to finalize the valuation and accounting for the acquisition as soon as practicable, but no later than one year after the acquisition date.

The purchase price consideration for the acquisition totaled \$204.7 million, of which \$141.3 million was in the form of cash and \$55.7 million was in the form of 1,096,583 shares of the Company's common stock. An additional payment of \$35 million will be paid to Contura if the Company is able to generate \$50 million in Bulkamid sales within a 12-month period before December 31, 2024. As the additional payment is contingent on future sales, the preliminary estimate of fair value was assessed to be \$7.6 million which is reflected as other long-term liabilities in the consolidated balance sheet. The cash consideration paid for the acquisition was funded by existing cash on hand.

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

	<b>Preliminary Purchase Price Allocation</b>
<b>Assets Acquired</b>	
Cash and cash equivalents	\$ 593
Accounts receivable	1,688
Inventory	988
Prepaid expenses and other current assets	115
Property and equipment	52
Other assets	108
Intangible assets	112,200
Total assets acquired	115,744
<b>Liabilities Assumed</b>	
Accounts payable	209
Accrued liabilities	820
Accrued compensation and benefits	315
Lease liability	86
Debt	122
Deferred tax liabilities	23,765
Total liabilities assumed	25,317
Net assets acquired	90,427
Purchase price consideration	204,692
Goodwill	\$ 114,265

#### *Intangible assets*

Identified intangible assets consist of technology, trade names and trademarks, and customer relationships. The fair value of each is being determined by a valuation specialist and the useful life determination was made by management. Both determinations were made in accordance with ASC 805 and are outlined in the table below:

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

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

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

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

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

Intangible assets will be amortized based on their useful life. \$2.0 million and \$4.6 million in amortization expense was recognized during the three and nine months ended September 30, 2021 in the consolidated statements of comprehensive loss. The unamortized balance as of September 30, 2021 was \$105.3 million. The total weighted-average original amortization period for the acquired finite-lived intangible assets is 12 years.

#### *Goodwill*

Goodwill is calculated as the excess of the consideration transferred over the fair value of the identifiable net assets acquired in a business combination and represents the future economic benefits expected to arise from anticipated synergies and intangible assets acquired that do not qualify for separate recognition, including an assembled workforce, noncontractual relationships, and other agreements. As an indefinite-lived asset, goodwill is not amortized but rather is subject to impairment testing on at least an annual basis. The Contura acquisition resulted in the preliminary recognition of \$114.3 million of goodwill, which is not expected to be deductible for tax purposes.

#### *Contingent consideration*

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

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

#### *Deferred tax liabilities*

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

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

#### Transaction-related costs

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

#### Pro forma

The following unaudited pro forma financial information presents the condensed consolidated results of operations of the Company with Contura for the three and nine months ended September 30, 2021 and 2020, and the year ended December 31, 2020 as if the acquisition had occurred on January 1, 2020 instead of February 25, 2021 (in thousands, except share and per share data). Contura's revenue and net income for the three months ended September 30, 2021 were \$6.8 million and \$5.2 million, respectively, of which \$6.8 million in revenue and \$5.2 million in net income was recognized after the February 25, 2021 acquisition date. Contura's revenue and net loss for the nine months ended September 30, 2021 were \$15.3 million and \$2.9 million, respectively, of which \$14.0 million in revenue and \$3.5 million in net loss was recognized after the February 25, 2021 acquisition date. Revenue and net loss recognized after the acquisition date were recorded within the Company's condensed consolidated statements of comprehensive loss. The pro forma information does not necessarily reflect the results of operations that would have occurred had the entities been a single company during the respective periods.

	Three Months Ended September 30,		Nine Months Ended September 30,		Year ended December 31,
	2021	2020	2021	2020	2020
Net revenue	\$ 46,913	\$ 38,208	\$ 128,508	\$ 83,989	\$ 122,444
Net loss	\$ (17,250)	\$ (10,024)	\$ (62,369)	\$ (51,424)	\$ (63,183)
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.25)	\$ (1.46)	\$ (1.37)	\$ (1.66)
Weighted-average shares used to compute basic and diluted net loss per share	44,848,023	39,927,507	42,656,984	37,409,567	38,077,918

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

- An adjustment to decrease net loss for the three and nine months ended September 30, 2021 by none and \$4.4 million, respectively, to eliminate integration and acquisition related costs incurred by the Company and Contura and a corresponding increase to net loss for the three and nine months ended September 30, 2020 by none and \$4.4 million, respectively, to give effect to the integration and acquisition of Contura as if it had occurred on January 1, 2020.
- An adjustment to increase net loss for the three and nine months ended September 30, 2021 by none and \$1.3 million, respectively, and a corresponding increase to net loss for the three and nine months ended September 30, 2020 by \$1.9 million and \$5.8 million, respectively, to reflect amortization of the fair value adjustments for intangible assets as if the assets were acquired January 1, 2020.
- An adjustment to decrease net loss for the three and nine months ended September 30, 2020 by \$0.6 million and \$1.7 million, respectively, to reflect remeasurement of the fair value adjustments for deferred tax liabilities as if the liabilities were assumed January 1, 2020.

## Note 9. Goodwill and Intangible Assets

The change in the carrying amount of goodwill during the nine months ended September 30, 2021 included the following (in thousands):

December 31, 2020	\$	—
February 25, 2021 Acquisition		114,265
Foreign currency translation adjustment		(4,700)
September 30, 2021	\$	<u>109,565</u>

Intangible assets as of September 30, 2021 included the following (in thousands):

	Weighted-Average Amortization Period	September 30, 2021			Intangible Assets, Net
		Gross Carrying Amount	Accumulated Amortization	Foreign currency translation adjustment	
Patent license asset	8.71 years	\$ 1,000	(890)	—	\$ 110
Exclusive license asset	4 years	\$ 3,300	(440)	—	\$ 2,860
Technology	12 years	\$ 81,100	(4,004)	(1,690)	\$ 75,406
Trade names and trademarks	Indefinite	\$ 19,700	—	(440)	\$ 19,260
Customer relationships	12 years	\$ 11,400	(564)	(170)	\$ 10,666
		<u>\$ 116,500</u>	<u>\$ (5,898)</u>	<u>\$ (2,300)</u>	<u>\$ 108,302</u>

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

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

## 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, 2020, as filed with the SEC on March 1, 2021.*

### Overview

We are a global medical technology company that develops and commercializes minimally invasive products to treat urinary and fecal dysfunction, including: (i) an implantable rechargeable sacral neuromodulation (SNM) system to treat urinary urge incontinence (UUI) and urinary urgency frequency (UUF), together referred to as overactive bladder (OAB), as well as fecal incontinence (FI), and non-obstructive urinary retention (UR); and (ii) a urethral bulking agent to treat female stress urinary incontinence (SUI).

OAB affects an estimated 87 million adults in the United States and Europe. Another estimated 40 million adults are reported to suffer from FI and another estimated 20 million women suffer from SUI.

SNM therapy is an effective and durable treatment for UUI, UUF, UR and FI that has been widely used and reimbursed in Europe and the United States for the past two decades. Bulkamid is also an effective and durable

treatment for SUI. Bulkamid was approved by the FDA for use in the United States in early 2020 and is widely reimbursed in the United States and most international markets.

SNM is the only OAB treatment with proven clinical superiority to standard medical therapy and OAB patients who receive SNM report significantly higher quality of life than patients undergoing drug treatment.

We estimate the global SNM market is now approximately \$650 million to \$700 million and believe it is a growing market that is currently less than three percent penetrated. Until we entered the market, it was serviced by Medtronic as a single participant.

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

We have marketing approvals for the r-SNM System in Europe, Canada, and Australia for all relevant clinical indications and initiated limited commercial efforts in England, the Netherlands and Canada in late 2018 and subsequently in Germany and Switzerland.

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

We are primarily focused on commercializing our products in the United States, which accounts for the vast majority of SNM sales worldwide. We have established a significant commercial infrastructure of sales personnel and clinical specialists and we continue to make significant investments to build our commercial organization to market and support our products. When making hiring decisions for these roles, we prioritize individuals with strong sales backgrounds and experience in neurostimulation applications, and who also have existing relationships with urologists and urogynecologists.

In February 2021, the FDA approved a third-generation INS for our r-SNM System under a PMA supplement. The third-generation INS upgrades the embedded software in the INS and the functionality of the patient remote control. These modifications give patients the ability to make broader stimulation parameter adjustments at home, including selecting a second therapy program that was set post-operatively based on interoperative findings. We intend to continue to make investments in research and development efforts to develop enhancements to our r-SNM System.

On February 25, 2021, we acquired Contura Limited (Contura) and its Bulkamid product, a urethral bulking agent indicated for the treatment of female SUI. In consideration for the acquisition, we paid approximately \$141.3 million in cash and issued 1,096,583 shares of our common stock. We may pay an additional \$35 million in the event Bulkamid sales in any consecutive 12-month period exceed \$50 million before December 31, 2024. As part of the transaction, we entered into a supply agreement with Contura International A/S (Contura International) to manufacture Bulkamid for us (Manufacturing and Supply Agreement). We have a right to a technology transfer after June 30, 2022 that would enable us to insource the manufacturing of Bulkamid. Bulkamid received a CE Mark in 2003 and a PMA from the FDA in 2020 and is sold through a combination of a direct sales force in the United States and certain European countries and distributors in certain international markets. The acquisition of Contura has expanded our international operations.

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

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

In late June 2021, we filed a PMA supplement with the FDA for our newly developed, long-lived, non-rechargeable SNM system. The non-rechargeable INS will utilize a primary cell battery with an expected life of at least 10 years with standard stimulation parameters. The non-rechargeable INS that has been submitted for approval is 11cc in volume, utilizes constant current stimulation and a recharge-free patient remote control, and is expected to be MRI compatible with 1.5T and 3.0T scanners.

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

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

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

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

We incurred net losses of \$64.9 million and \$43.6 million for the nine months ended September 30, 2021 and 2020, respectively, and had an accumulated deficit of \$299.4 million as of September 30, 2021 compared to \$234.5 million at December 31, 2020. As of September 30, 2021, we had available cash and cash equivalents of approximately \$228.8 million, current liabilities of approximately \$27.8 million, and long-term liabilities of approximately \$43.5 million.

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

On May 12, 2020, we completed a follow-on offering by issuing 4,600,000 shares of common stock, at an offering price of \$32.50 per share, inclusive of 600,000 shares of our common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The gross proceeds to us from this follow-on offering were \$149.5 million and the net proceeds were approximately \$140.5 million, after deducting underwriting discounts, commissions and offering expenses payable by us.

#### **May 2021 Follow-On Offering**

On May 14, 2021, we completed a follow-on offering by issuing 4,025,000 shares of common stock, at an offering price of \$50.00 per share, inclusive of 525,000 shares of our common stock issued upon the exercise by the underwriters of their option to purchase additional shares. The gross proceeds to us from this follow-on offering were \$201.3 million and the net proceeds were approximately \$190.0 million, after deducting underwriting discounts, commissions and offering expenses payable by us.

#### **Impact of COVID-19**

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

May 2020 and continued to improve in the second half of 2020 through the second quarter of 2021. During the third quarter of 2021, certain outpatient elective procedures were again postponed or cancelled related to the COVID-19 pandemic and specifically the Delta variant, which adversely affected our business during the third quarter.

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

### **AMF License Agreement**

On October 1, 2013, we entered into a license agreement (the License Agreement) with the Alfred E. Mann Foundation for Scientific Research (AMF), pursuant to which AMF licensed us certain patents and know-how (AMF IP), relating to, in relevant part, an implantable pulse generator and related system components in development by AMF as of that date, in addition to any peripheral or auxiliary devices, including all components, that when assembled, comprise such device, excluding certain implantable pulse generators (AMF Licensed Products).

Under the License Agreement, for each calendar year beginning in 2018, we are obligated to pay AMF a royalty on an AMF Licensed Product-by-AMF Licensed Product basis if one of the following conditions applies: (i) one or more valid claims within any of the patents licensed to us by AMF covers such AMF Licensed Products or the manufacture of such AMF Licensed Products or (ii) for a period of 12 years from the first commercial sale anywhere in the world of such AMF Licensed Product, in each case. The foregoing royalty is calculated as the greater of (a) 4% of all net revenue derived from the AMF Licensed Products, and (b) a minimum annual royalty (the Minimum Royalty), payable quarterly. The Minimum Royalty automatically increases each year, subject to a maximum amount of \$200,000 per year. During the three and nine months ended September 30, 2021, we have recorded royalties of \$1.6 million and \$4.5 million, respectively. During the three and nine months ended September 30, 2020, we have recorded royalties of \$1.4 million and \$3.0 million, respectively. We have 60 days to pay AMF the royalty amount due under the License Agreement, and if we fail to pay AMF within such 60-day period, AMF may, at its election, convert the exclusive license to a non-exclusive license or terminate the License Agreement.



**Components of Our Results of Operations****Net Revenue**

Revenue during the three and nine months ended September 30, 2021 and 2020 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>SNM net revenue</b>				
United States	\$ 39,147	\$ 34,139	\$ 110,135	\$ 73,833
International markets	922	1,104	3,031	2,919
	\$ 40,069	\$ 35,243	\$ 113,166	\$ 76,752
<b>Bulkamid net revenue</b>				
United States	\$ 3,921	\$ —	\$ 6,870	\$ —
International markets	2,923	—	7,119	—
	\$ 6,844	\$ —	\$ 13,989	\$ —
<b>Total net revenue</b>	<b>\$ 46,913</b>	<b>\$ 35,243</b>	<b>\$ 127,155</b>	<b>\$ 76,752</b>

**Cost of Goods Sold and Gross Margin**

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

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

**Research and Development Expenses**

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

The following table summarizes our research and development expenses by functional area for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Personnel related	\$ 4,604	\$ 3,273	\$ 14,338	\$ 8,072
Clinical development	287	107	613	292
Contract R&D and manufacturing	1,877	2,692	6,892	8,373
Royalty expense	1,607	1,406	4,520	3,030
Other R&D expenses	273	241	752	1,177
Total R&D expenses	<u>\$ 8,648</u>	<u>\$ 7,719</u>	<u>\$ 27,115</u>	<u>\$ 20,944</u>

#### **General and Administrative Expenses**

General and administrative expenses consist primarily of employee compensation, including stock-based compensation, and spending related to finance, information technology, human resource functions, consulting, legal, and professional service fees. Other general and administrative expenses include director and officer insurance premiums, investor relations costs, changes in fair value of the contingent consideration, office-related expenses, facilities and equipment rentals, bad debt expense, and travel expenses. We expect our general and administrative expenses will significantly increase in absolute dollars as we increase our headcount and expand administrative personnel to support our growth and operations as a public company including finance personnel and information technology services. Additionally, we anticipate increased legal expenses associated with our patent infringement litigation with Medtronic. These expenses will further increase as we no longer qualify as an “emerging growth company” under the Jumpstart Our Business Startups (JOBS) Act, which requires us to comply with certain additional reporting requirements effective December 31, 2020. We expect general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

#### **Sales and Marketing Expenses**

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

#### **Amortization of Intangible Assets**

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

#### **Acquisition-Related Costs**

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

#### **Other Expense, Net**

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

### Income Tax Expense

Income tax expense primarily consists of a remeasurement of deferred tax liabilities in our foreign operations, net of losses 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 and nine months ended September 30, 2021 and 2020 (in thousands, except percentages):

	Three Months Ended September 30,		Period to Period Change	Nine Months Ended September 30,		Period to Period Change
	2021	2020		2021	2020	
Net revenue	\$ 46,913	\$ 35,243	\$ 11,670	\$ 127,155	\$ 76,752	\$ 50,403
Cost of goods sold	15,719	13,434	2,285	46,828	31,792	15,036
Gross profit	31,194	21,809	9,385	80,327	44,960	35,367
Gross Margin	66.5 %	61.9 %		63.2 %	58.6 %	
<b>Operating Expenses</b>						
Research and development	8,648	7,719	929	27,115	20,944	6,171
General and administrative	8,720	5,773	2,947	23,381	18,963	4,418
Sales and marketing	28,112	17,057	11,055	74,451	47,846	26,605
Amortization of intangible assets	2,216	29	2,187	5,094	86	5,008
Acquisition-related costs	—	—	—	4,414	—	4,414
Total operating expenses	47,696	30,578	17,118	134,455	87,839	46,616
Loss from operations	(16,502)	(8,769)	(7,733)	(54,128)	(42,879)	(11,249)
<b>Other Expense</b>						
Interest income	9	35	(26)	24	742	(718)
Interest and other expense	(229)	(434)	205	(7,528)	(1,429)	(6,099)
Other expense, net	(220)	(399)	179	(7,504)	(687)	(6,817)
Loss before income tax expense	(16,722)	(9,168)	(7,554)	(61,632)	(43,566)	(18,066)
Income tax expense	528	—	528	3,269	1	3,268
Net loss	(17,250)	(9,168)	(8,082)	(64,901)	(43,567)	(21,334)
Foreign currency translation adjustment	(5,138)	99	(5,237)	(6,481)	(186)	(6,295)
Comprehensive loss	\$ (22,388)	\$ (9,069)	\$ (13,319)	\$ (71,382)	\$ (43,753)	\$ (27,629)

### Comparison of the Three Months Ended September 30, 2021 and 2020

#### Net Revenue

Net revenue was \$46.9 million for the three months ended September 30, 2021 and was primarily derived from the sale of our products to customers in the United States and certain international markets. Net revenue was \$35.2 million for the three months ended September 30, 2020 and was derived from the sale of our r-SNM System to customers in the United States, Europe and Canada. The increase in net revenue is primarily due to the addition of \$6.8 million in Bulkamid sales and increased sales of our r-SNM System as we expanded our customer base in the U.S. and international markets. Sales during the three months ended September 30, 2021 were negatively impacted by the COVID-19 global pandemic.

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

We incurred \$15.7 million of cost of goods sold for the three months ended September 30, 2021. We incurred \$13.4 million of cost of goods sold for the three months ended September 30, 2020. Gross margin was 66.5% in the three months ended September 30, 2021, compared to 61.9% for the three months ended September 30, 2020. The increase in gross margin is primarily due to increased efficiencies resulting in higher absorption rates.

### *Research and Development Expenses*

Research and development expenses increased \$0.9 million, or 12.1%, to \$8.6 million in the three months ended September 30, 2021, compared to \$7.7 million in the three months ended September 30, 2020. The increase in research and development expenses was primarily attributable to an increase of \$1.3 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits.

### *General and Administrative Expenses*

General and administrative expenses increased \$2.9 million, or 51.0%, to \$8.7 million in the three months ended September 30, 2021, compared to \$5.8 million in the three months ended September 30, 2020, primarily as a result of an increase of \$1.3 million in the change in fair value of the contingent consideration, \$0.9 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits and an increase of \$0.4 million in legal and consulting costs.

### *Sales and Marketing Expenses*

Sales and marketing expenses increased \$11.1 million, or 64.8%, to \$28.1 million in the three months ended September 30, 2021, compared to \$17.1 million in the three months ended September 30, 2020. The increase in sales and marketing expenses was primarily due to an increase of \$7.5 million related to personnel costs including salaries, wages, sales personnel commissions, stock-based compensation and other employee-related benefits, an increase of \$1.8 million related to direct-to-consumer programs and other advertising expenses, and an increase of \$0.9 million related to travel expenses.

### *Amortization of Intangible Assets*

Amortization of intangible assets increased to \$2.2 million in the three months ended September 30, 2021, compared to minimal amortization of intangible assets in the three months ended September 30, 2020. The increase in amortization of intangible assets was primarily due to an increase of technology and customer relationships acquired related to the Contura acquisition.

### *Acquisition-Related Costs*

We recorded no acquisition-related costs for the three months ended September 30, 2021 and 2020.

### *Other Expense, Net*

Other expense, net was \$0.2 million in the three months ended September 30, 2021 consisting primarily of losses on foreign currency transactions. Other expense, net was \$0.4 million in the three months ended September 30, 2020 consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank, partially offset by interest income earned on cash equivalents.

### *Income Tax Expense*

Income tax expense was \$0.5 million for the three months ended September 30, 2021 primarily related to the change in deferred tax liabilities generated in our foreign operations related to the Contura acquisition. We recorded no income tax expense for the three months ended September 30, 2020.

## **Comparison of the Nine Months Ended September 30, 2021 and 2020**

### *Net Revenue*

Net revenue was \$127.2 million for the nine months ended September 30, 2021 and was primarily derived from the sale of our products to customers in the United States and certain international markets. Net revenue was \$76.8 million for the nine months ended September 30, 2020 and was derived from the sale of our r-SNM System to customers in the United States, Europe and Canada. The increase in net revenue is primarily due to increased sales of our r-SNM System as we expanded our customer base in the U.S. and international markets and the addition of \$14.0 million in Bulkamid sales. Sales during the nine months ended September 30, 2020 were also more severely impacted by the COVID-19 global pandemic, with the initial restrictions on elective procedures occurring during the second quarter of 2020.

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

We incurred \$46.8 million of cost of goods sold for the nine months ended September 30, 2021. We incurred \$31.8 million of cost of goods sold for the nine months ended September 30, 2020. Gross margin was 63.2% in the nine months ended September 30, 2021, compared to 58.6% for the nine months ended September 30, 2020. The increase in gross margin is primarily due to increased efficiencies resulting in higher absorption rates.

### *Research and Development Expenses*

Research and development expenses increased \$6.2 million, or 29.3%, to \$27.1 million in the nine months ended September 30, 2021, compared to \$20.9 million in the nine months ended September 30, 2020. The increase in research and development expenses was primarily attributable to an increase of \$6.3 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits.

### *General and Administrative Expenses*

General and administrative expenses increased \$4.4 million, or 23.3%, to \$23.4 million in the nine months ended September 30, 2021, compared to \$19.0 million in the nine months ended September 30, 2020, primarily as a result of an increase of \$2.5 million in personnel costs including salaries and wages, stock-based compensation and other employee-related benefits, an increase of \$1.3 million in the change in fair value of the contingent consideration, partially offset by a decrease of \$0.5 million in bad debt expense.

### *Sales and Marketing Expenses*

Sales and marketing expenses increased \$26.6 million, or 55.6%, to \$74.5 million in the nine months ended September 30, 2021, compared to \$47.8 million in the nine months ended September 30, 2020. The increase in sales and marketing expenses was primarily due to an increase of \$17.8 million related to personnel costs including salaries, wages, sales personnel commissions, stock-based compensation and other employee-related benefits, an increase of \$4.1 million related to direct-to-consumer programs and other advertising expenses, and an increase of \$1.9 million related to travel expenses.

### *Amortization of Intangible Assets*

Amortization of intangible assets increased to \$5.1 million in the nine months ended September 30, 2021, compared to \$0.1 million in the nine months ended September 30, 2020. The increase in amortization of intangible assets was primarily due to an increase of technology and customer relationships acquired related to the Contura acquisition.

### *Acquisition-Related Costs*

Acquisition-related costs was \$4.4 million in the nine months ended September 30, 2021 related to the Contura acquisition.

### *Other Expense, Net*

Other expense, net was \$7.5 million in the nine months ended September 30, 2021 consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank. Other expense, net was \$0.7 million in the nine months ended September 30, 2020 consisting primarily of interest expense incurred related to the Loan Agreement with Silicon Valley Bank, partially offset by interest income earned on cash equivalents. The

increase in other expense, net primarily relates to interest on higher outstanding debt balances during the nine months ended September 30, 2021 and the related write-off of unamortized debt issuance costs.

#### *Income Tax Expense*

Income tax expense was \$3.3 million for the nine months ended September 30, 2021 primarily related to the remeasurement of our U.K. deferred tax liabilities due to an increase in the U.K. income tax rate from 19% to 25% which was enacted during the second quarter of 2021 and effective April 1, 2023, net of losses in certain foreign jurisdictions. We recorded minimal income tax expense for the nine months ended September 30, 2020.

#### **Liquidity and Capital Resources**

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

We incurred net losses of \$64.9 million and \$43.6 million for the nine months ended September 30, 2021 and 2020, respectively, and had an accumulated deficit of \$299.4 million as of September 30, 2021 compared to \$234.5 million at December 31, 2020. We expect to continue to spend a significant amount of our existing resources on sales and marketing activities as we continue to commercialize and market our products in the United States and internationally.

As of September 30, 2021, we had cash and cash equivalents of \$228.8 million compared to \$241.2 million at December 31, 2020. We expect that our cash and cash equivalents on hand will be sufficient to fund our operations through at least the next 12 months. We fund our operations through a combination of proceeds from public offerings of our common stock, cash receipts from sales of our r-SNM System and proceeds from our Loan Agreement with Silicon Valley Bank. As of September 30, 2021, we had \$0.1 million in outstanding borrowings.

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.

#### **Cash Flows**

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

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Net cash provided by (used in)		
Operating activities	\$ (40,530)	\$ (55,428)
Investing activities	(141,918)	10,677
Financing activities	170,311	143,135
Effect of exchange rate changes on cash and cash equivalents	(247)	(186)
Net (decrease) increase in cash and cash equivalents	<u>\$ (12,384)</u>	<u>\$ 98,198</u>

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

Net cash used in operating activities was \$40.5 million for the nine months ended September 30, 2021 and consisted primarily of a net loss of \$64.9 million and a decrease from changes in net operating assets of \$10.3 million, partially offset by non-cash charges of \$34.7 million. Net operating assets consisted primarily of inventory and accounts receivable due to the commercial growth of our r-SNM System in the United States and the addition of Bulkamid sales. Non-cash charges consisted primarily of stock-based compensation and depreciation and amortization.

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

*Net cash (used in) provided by investing activities*

Net cash used in investing activities was \$141.9 million for the nine months ended September 30, 2021 and consisted primarily of the \$140.7 million paid for the acquisition of Contura.

Net cash provided by investing activities was \$10.7 million for the nine months ended September 30, 2020 and consisted primarily of sales and maturities of short-term investments, partially offset by purchases of property and equipment.

*Net cash provided by financing activities*

Net cash provided by financing activities was \$170.3 million for the nine months ended September 30, 2021 and consisted primarily of \$190.0 million in net proceeds received in the May 2021 follow-on offering, partially offset by a net debt repayment of \$26.0 million.

Net cash provided by financing activities was \$143.1 million for the nine months ended September 30, 2020 and consisted primarily of \$140.5 million in net proceeds received in the May 2020 follow-on offering.

**Indebtedness**

In June 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to the term loan under the Loan and Security Agreement with Silicon Valley Bank entered into in February 2021, were paid in full. The unamortized debt issuance costs of \$4.4 million as of March 31, 2021 was expensed and recognized as interest expense during the three months ended June 30, 2021.

In January 2021, the principal amount, accrued interest, accrued loan fees, and prepayment fees related to the term loan under the Loan and Security Agreement with Silicon Valley Bank entered into in February 2018, were paid in full. The unamortized debt issuance costs of \$0.4 million as of December 31, 2020 was expensed and recognized as interest expense during the three months ended March 31, 2021.

We have no further indebtedness arrangements.

**Off-Balance Sheet Arrangements**

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

**Contractual Obligations**

Refer to the Liquidity and Capital Resources—Indebtedness section above for changes in debt obligations during the first half of fiscal year 2021; there were no other material changes to our long-term contractual obligations as reported in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the SEC on March 1, 2021

**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, 2020, as filed with the SEC on March 1, 2021. We have reviewed and determined that those critical accounting policies and estimates remain our critical accounting policies and estimates as of and for the nine months ended September 30, 2021.

## **Recent Accounting Pronouncements**

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

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

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

### ***Interest Rate Risk***

We had cash and cash equivalents of \$228.8 million as of September 30, 2021, which came from public offerings of our common stock and debt financing arrangements. The goals of our investment policy are liquidity and capital preservation and we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash and cash equivalents. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

### ***Foreign Currency Exchange Rate Risk***

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

### ***Inflation Risk***

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

## **Item 4. Controls and Procedures.**

### ***Limitations on effectiveness of controls and procedures***

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

### ***Evaluation of disclosure controls and procedures***

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2021.



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

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2021 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, 2020, as filed with the SEC on March 1, 2021, during the quarter ended September 30, 2021.

**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, 2020, as filed with the SEC on March 1, 2021. 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**

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

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

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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.

Date: November 4, 2021

By:

**AXONICS, INC.**

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer and Director

(Principal Executive Officer)

Date: November 4, 2021

By:

/s/ Dan L. Dearen

Dan L. Dearen

President and Chief Financial Officer

(Principal Financial and Accounting Officer)

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: November 4, 2021

By:

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

I, Dan L. Dearen, certify that:

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

Date: November 4, 2021

By:

/s/ Dan L. Dearen

Dan L. Dearen

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



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

In connection with the Quarterly Report of Axonics, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 4, 2021

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.