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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2022**
**OR**

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

**For transition period from to**
**Commission File Number 001-40337**

# NEUROPACE, INC.
(Exact name of registrant as specified in its charter)

| **Delaware** | **22-3550230** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |

**455 N. Bernardo Avenue**
**Mountain View, CA 94043**
**(650) 237-2700**
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.001 par value per share | NPCE | Nasdaq Global Market |

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☒ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities 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 4, 2022, there were approximately 24,903,146 shares of the registrant's common stock outstanding.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements regarding results or events that may occur in the future contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial condition, as well as expectations of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would,” or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, factors and assumptions more thoroughly described in “Risk Factors.” These risks are not exhaustive. Other sections of this Quarterly Report on Form 10-Q, as well as our other disclosures and filings, include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ from those contained in, or implied by, any forward-looking statements.

You should not rely on these forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q or to conform these statements to actual results or to changes in our expectations, whether as a result of any new information, future events, changed circumstances or otherwise. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our expected future growth;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- our ability to accurately forecast demand for our products;
- our expectations regarding the impact of the COVID-19 pandemic on our sales, business, financial condition and results of operations;
- the rate and degree of market acceptance of our products;
- coverage and reimbursement for procedures performed using our products, including pre-implant evaluations, implant procedures, and follow-up care;
- the performance of third parties in connection with the manufacturing and development of our products, including single-source suppliers;
- regulatory developments in the United States and in any foreign countries in which we may seek to do business;
- our ability to retain regulatory approval for our products or obtain regulatory approval for updates to our products, or new products or indications in the United States and in any foreign countries in which we may seek to do business;
- our research and development for existing products and new products;
- our reliance on third-party suppliers for product components, some of which are single source suppliers;

- our ability to manufacture our products in conformity with FDA requirements and with regulatory requirements of any foreign countries in which we may seek to do business;
- our ability to predict product performance;
- our ability to retain or scale our organizational culture;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our ability to retain and hire our board of directors, senior management, or operational personnel;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act and as a smaller reporting company under the federal securities laws;
- our ability to develop and maintain our corporate infrastructure, including our ability to maintain an effective system of internal controls;
- our financial performance and capital requirements; and
- our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for our products and technology, as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

You should read this Quarterly Report on Form 10-Q as well as the documents that we reference in, and have filed as exhibits to, this report 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.

## PART I. FINANCIAL INFORMATION

**Item 1. Unaudited Financial Statements**

# NeuroPace, Inc.
## Condensed Balance Sheets
## (unaudited)

| *(in thousands, except share and per share amounts)* | September 30, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 5,688 | $ 19,187 |
| Short-term investments | 79,724 | 96,397 |
| Accounts receivable | 7,876 | 7,091 |
| Inventory | 8,581 | 7,822 |
| Prepaid expenses and other current assets | 2,501 | 2,319 |
| Total current assets | 104,370 | 132,816 |
| Property and equipment, net | 894 | 603 |
| Operating lease right-of-use asset | 15,067 | — |
| Restricted cash | 122 | 122 |
| Other assets | 21 | 21 |
| Total assets | $ 120,474 | $ 133,562 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 1,175 | $ 1,378 |
| Accrued liabilities | 7,550 | 7,923 |
| Operating lease liability | 692 | — |
| Total current liabilities | 9,417 | 9,301 |
| Deferred rent, noncurrent | — | 911 |
| Long-term debt | 51,954 | 49,847 |
| Operating lease liability, net of current portion | 15,694 | — |
| Total liabilities | 77,065 | 60,059 |
| Commitments and contingencies (Note 5) | | |
| Stockholders' equity | | |
| Preferred stock, $0.001 par value, 10,000,000 shares authorized and no shares issued and outstanding as of September 30, 2022 and December 31, 2021 | — | — |
| Common stock, $0.001 par value, 200,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 24,864,119 and 24,452,999 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively | 25 | 24 |
| Additional paid-in capital | 504,425 | 497,522 |
| Accumulated other comprehensive loss | (1,334) | (272) |
| Accumulated deficit | (459,707) | (423,771) |
| Total stockholders' equity | 43,409 | 73,503 |
| Total liabilities and stockholders' equity | $ 120,474 | $ 133,562 |

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

# NeuroPace, Inc.
## Condensed Statements of Operations and Comprehensive Loss
## (unaudited)

| *(in thousands, except share and per share amounts)* | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Revenue | $ 11,157 | $ 10,339 | $ 32,731 | $ 34,186 |
| Cost of goods sold | 3,192 | 2,832 | 9,041 | 8,827 |
| Gross profit | 7,965 | 7,507 | 23,690 | 25,359 |
| **Operating expenses** | | | | |
| Research and development | 5,611 | 4,329 | 16,857 | 12,866 |
| Selling, general and administrative | 12,553 | 9,421 | 37,768 | 27,215 |
| Total operating expenses | 18,164 | 13,750 | 54,625 | 40,081 |
| Loss from operations | (10,199) | (6,243) | (30,935) | (14,722) |
| Interest income | 423 | 136 | 778 | 262 |
| Interest expense | (1,906) | (1,826) | (5,588) | (5,548) |
| Other income (expense), net | (103) | (150) | (191) | (5,379) |
| Net loss | $ (11,785) | $ (8,083) | $ (35,936) | $ (25,387) |
| Unrealized gain (loss) on available-for-sale debt securities | 117 | 22 | (1,062) | — |
| Comprehensive loss | $ (11,668) | $ (8,061) | $ (36,998) | $ (25,387) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.48) | $ (0.34) | $ (1.47) | $ (1.81) |
| Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted | 24,728,701 | 24,101,399 | 24,514,820 | 14,061,958 |

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

# NeuroPace, Inc.
## Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
## (unaudited)

| *(in thousands, except share amounts)* | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balances as of January 1, 2022 | 24,452,999 | $ 24 | $ 497,522 | $ (272) | $ (423,771) | $ 73,5 |
| Net loss | — | — | — | — | (11,461) | (11,4 |
| Unrealized loss on available-for-sale debt securities | — | — | — | (710) | — | (7 |
| Issuance of common stock pursuant to stock option exercises | 38,635 | — | 1 | — | — | |
| Repurchase of common stock | (14,454) | — | — | — | — | |
| Change in early exercise liability | — | — | 2 | — | — | |
| Stock-based compensation | — | — | 1,488 | — | — | 1,4 |
| Balances as of March 31, 2022 | 24,477,180 | 24 | 499,013 | (982) | (435,232) | 62,8 |
| Net loss | — | — | — | — | (12,690) | (12,6 |
| Unrealized loss on available-for-sale debt securities | — | — | — | (469) | — | (4 |
| Issuance of common stock pursuant to stock option exercises | 74,435 | — | 2 | — | — | |
| Issuance of common stock pursuant to Employee Stock Purchase Plan | 147,217 | 1 | 678 | — | — | 6 |
| Issuance of common stock upon vesting of restricted stock units | 121,656 | — | — | — | — | |
| Shares withheld for taxes | (5,633) | — | (47) | — | — | ( |
| Change in early exercise liability | — | — | 1 | — | — | |
| Stock-based compensation | — | — | 2,603 | — | — | 2,6 |
| Balances as of June 30, 2022 | 24,814,855 | 25 | 502,250 | (1,451) | (447,922) | 52,9 |
| Net loss | — | — | — | — | (11,785) | (11,7 |
| Unrealized gain on available-for-sale debt securities | — | — | — | 117 | — | 1 |
| Issuance of common stock pursuant to stock option exercises | 16,130 | — | — | — | — | |
| Issuance of common stock upon vesting of restricted stock units | 34,540 | — | — | — | — | |
| Shares withheld for taxes | (1,406) | — | (7) | — | — | |
| Stock-based compensation | — | — | 2,182 | — | — | 2,1 |
| Balances as of September 30, 2022 | 24,864,119 | $ 25 | $ 504,425 | $ (1,334) | $ (459,707) | $ 43,4 |

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

# NeuroPace, Inc.
## Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
## (unaudited)

| *(in thousands, except share amounts)* | Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders Equity (Defic |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| Balances as of January 1, 2021 | 16,614,178 | $ 141,422 | 314,096 | $ — | $ 239,826 | $ 33 | $ (387,691) | $ (147,8 |
| Net loss | — | — | — | — | — | — | (8,810) | (8,8 |
| Issuance of common stock pursuant to stock option exercises | — | — | 156,538 | — | 4 | — | — | |
| Stock-based compensation | — | — | — | — | 202 | — | — | 2 |
| Balances as of March 31, 2021 | 16,614,178 | $ 141,422 | 470,634 | — | 240,032 | 33 | (396,501) | (156,4 |
| Net loss | — | — | — | — | — | — | (8,494) | (8,4 |
| Unrealized loss on available-for-sale debt securities | — | — | — | — | — | (22) | — | ( |
| Net exercise of Series B' redeemable convertible preferred stock warrants | 213,941 | 5,606 | — | — | — | — | — | |
| Conversion of redeemable convertible preferred stock into common stock | (16,828,119) | (147,028) | 16,828,119 | 17 | 147,011 | — | — | 147,0 |
| Net exercise of common stock warrants | — | — | 185 | — | — | — | — | |
| Issuance of common stock upon initial public offering, net of issuance costs and underwriting discount of $11,813 | — | — | 6,900,000 | 7 | 105,480 | — | — | 105,4 |
| Issuance of common stock pursuant to stock option exercises | — | — | 95,770 | — | 4 | — | — | |
| Change in early exercise liability | — | — | — | — | (4) | — | — | |
| Stock-based compensation | — | — | — | — | 1,103 | — | — | 1,1 |
| Balances as of June 30, 2021 | — | $ — | 24,294,708 | 24 | 493,626 | 11 | (404,995) | 88,6 |
| Net loss | — | — | — | — | — | — | (8,083) | (8,0 |
| Unrealized gain on available-for-sale debt securities | — | — | — | — | — | 22 | — | |
| Issuance of common stock pursuant to stock option exercises | — | — | 13,190 | — | — | — | — | |
| Stock-based compensation | — | — | — | — | 1,107 | — | — | 1,1 |
| Balances as of September 30, 2021 | — | $ — | 24,307,898 | $ 24 | $ 494,733 | $ 33 | $ (413,078) | $ 81,7 |

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

# NeuroPace, Inc.
## Condensed Statements of Cash Flows
## (unaudited)

| *(in thousands)* | Nine Months Ended September 30, 2022 | 2021 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Net loss | $ (35,936) | $ (25,387) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Stock-based compensation expense | 6,273 | 2,412 |
| Depreciation | 213 | 217 |
| Amortization of debt discount and issuance costs | 192 | 200 |
| Non-cash interest expense | 636 | 608 |
| PIK interest incurred but not paid on term loan | 1,279 | — |
| Amortization of right-of-use asset | 2,022 | — |
| Realized loss from sale of short-term investments | 210 | — |
| Inventory write-downs | 204 | 185 |
| Change in fair value of redeemable convertible preferred stock warrant liability | — | 5,236 |
| Changes in operating assets and liabilities | | |
| Accounts receivable | (783) | 1,784 |
| Inventory | (964) | (438) |
| Prepaid expenses and other assets | (181) | (2,227) |
| Accounts payable | (208) | 259 |
| Accrued liabilities | 121 | 1,296 |
| Operating lease liabilities | (2,104) | — |
| Deferred rent | — | (519) |
| Net cash (used in) operating activities | (29,026) | (16,374) |
| **Cash flows from investing activities** | | |
| Acquisition of property and equipment | (501) | (230) |
| Proceeds from sale of short-term investments | 15,400 | — |
| Purchase of short-term investments | — | (85,012) |
| Net cash provided by (used in) investing activities | 14,899 | (85,242) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common stock under employee plans | 683 | 8 |
| Taxes withheld and paid related to net share settlement of equity awards | (55) | — |
| Proceeds from issuance of common stock in initial public offering, net of underwriter discount and commissions | — | 109,089 |
| Payment of deferred offering costs | — | (3,392) |
| Repayment of debt | — | (4,090) |
| Net cash provided by financing activities | 628 | 101,615 |
| Net (decrease) in cash and cash equivalents | (13,499) | (1) |
| Cash, cash equivalents and restricted cash | | |
| Beginning of the period | 19,309 | 26,756 |
| End of the period | $ 5,810 | $ 26,755 |
| Reconciliation of cash, cash equivalents and restricted cash to balance sheets: | | |
| Cash and cash equivalents | $ 5,688 | $ 26,633 |
| Restricted cash | 122 | 122 |
| Cash, cash equivalents and restricted cash in balance sheets | $ 5,810 | $ 26,755 |

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

# NeuroPace, Inc.
## Condensed Statements of Cash Flows
## (unaudited)

| | | | | |
|---|---|---|---|---|
| **Supplemental disclosure of cash flow information:** | | | | |
| Cash paid for interest | $ | 3,481 | $ | 4,740 |
| **Supplemental disclosures of non-cash investing and financing information:** | | | | |
| Operating lease right-of-use asset obtained in exchange for lease obligations | $ | 10,585 | $ | — |
| Net change in accrued liabilities from early exercise of options | $ | (3) | $ | 4 |
| Purchase of property and equipment included in accounts payable | $ | 4 | $ | 97 |

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

## 1. The Company

NeuroPace, Inc., or the Company, was incorporated in the state of Delaware on November 19, 1997. The Company is a commercial-stage medical device company that has developed the RNS System, the only commercially available brain-responsive neuromodulation system designed for treating medically refractory focal epilepsy by delivering personalized, real-time treatment at the seizure source. The Company began commercializing its products in the United States in 2014.

### Initial Public Offering

On April 21, 2021, the Company's registration statement on Form S-1 (File No. 333-254663) relating to its initial public offering, or IPO, of common stock became effective. The IPO closed on April 26, 2021, at which time the Company issued 6,900,000 shares of its common stock at a price of $17.00 per share, which included the issuance of shares in connection with the exercise by the underwriters of their option to purchase up to 900,000 additional shares. The Company received an aggregate of $117.3 million in gross proceeds, before underwriting discounts and commissions and offering costs, and approximately $105.5 million in net proceeds after deducting $8.2 million in underwriting discounts and commissions and $3.6 million in offering costs.

Upon the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock converted into 16,614,178 shares of common stock, warrants to purchase 346,823 shares of Series B' convertible preferred stock net exercised to 213,941 shares of Series B' convertible preferred stock and subsequently converted into common stock on a one-to-one basis, and warrants to purchase 219 shares of common stock net exercised to 185 shares of common stock. In connection with the completion of its IPO, on April 26, 2021, the Company's certificate of incorporation was amended and restated to provide for 200,000,000 authorized shares of common stock with a par value of $0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.001 per share.

### Liquidity and Capital Resources

The Company has incurred operating losses and negative cash flows from operations since its inception and has an accumulated deficit of $459.7 million as of September 30, 2022. For the nine months ended September 30, 2022 and 2021, the Company used $29.0 million and $16.4 million of cash, respectively, in its operating activities. As of September 30, 2022, the Company had cash, cash equivalents and short-term investments of $85.4 million. Historically, the Company has funded its operations principally through the sales of its products, issuance of redeemable convertible preferred stock and debt financing. On April 26, 2021, the Company completed its IPO and received approximately $105.5 million in net proceeds after deducting underwriting discounts, commissions and offering costs.

The Company's condensed financial statements have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Management believes that the Company's cash, cash equivalents and short-term investments will allow the Company to continue its planned operations for at least the next 12 months from the date of the issuance of these unaudited interim condensed financial statements.

In connection with the Term Loan described in Note 6, the Company will need to be in compliance with a minimum annual net revenue covenant determined in accordance with generally accepted accounting principles of $43.0 million in the year ended December 31, 2022, and maintain a minimum cash and cash equivalents balance of $5.0 million. If the Company cannot generate sufficient revenue in the future, the Company may not be in compliance with the annual net revenue covenant and the lender may call the debt resulting in the Company immediately needing additional funds, and resulting in a going concern. As of September 30, 2022, the Company was in compliance with all covenants of the Term Loan.

The COVID-19 pandemic is affecting business conditions in the industry in which the Company operates. Beginning in March 2020, the Company's net sales were negatively impacted by the COVID-19 pandemic as hospitals delayed or canceled elective procedures. In response to the pandemic, many state and local governments in the U.S. issued orders that temporarily precluded elective procedures in order to conserve scarce health system resources. The decrease in hospital admission rates and elective surgeries reduced both the number of patients being

evaluated for treatment with and demand for elective procedures using the Company's RNS System. A similar decrease occurred in the third and fourth quarters of 2021, as well as in the first half of 2022, as hospitals responded to new COVID-19 variants, including the Delta and Omicron variants. The Company has taken necessary precautions to safeguard its employees, patients, customers, and other stakeholders from the COVID-19 pandemic, while maintaining business continuity to support its patients, customers and employees. The timing, extent and continuation of any increase in procedures, and any corresponding increase in sales of the Company's products, and whether there could be a future decrease in the current level of procedures as a result of the COVID-19 pandemic or otherwise, remain uncertain and are subject to a variety of factors.

## 2. Summary of Significant Accounting Policies

### Basis of Presentation

The unaudited interim condensed financial statements have been prepared in conformity with generally accepted accounting principles in the United States, or GAAP, as defined by the Financial Accounting Standards Board, or the FASB.

### Reverse Stock Split

On April 9, 2021, the Company effected a 1-for-2.6 reverse stock split of its common stock and redeemable convertible preferred stock. The par value of the authorized stock was not adjusted as a result of the reverse stock split.

All issued and outstanding shares of common stock and redeemable convertible preferred stock and related per share amounts contained in the accompanying financial statements have been retroactively revised to reflect the combined effect of all reverse stock splits for all periods presented.

### Unaudited Interim Financial Information

The condensed balance sheet as of December 31, 2021 was derived from the Company's audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited condensed financial statements as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021, have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. Accordingly, these financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2021 and notes thereto, which are included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the SEC on March 10, 2022. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed financial position as of September 30, 2022 and condensed results of operations for the three and nine months ended September 30, 2022 and 2021 and condensed cash flows for the nine months ended September 30, 2022 and 2021 have been made. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

### Use of Estimates

The preparation of unaudited interim condensed financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. The Company uses significant judgment when making estimates related to the valuation of its common stock prior to the IPO, and related stock-based compensation, the valuation of deferred tax assets and related valuation allowances, provision for excess and obsolete inventories, and the valuation of redeemable convertible preferred stock warrant liability. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

**Fair Value of Financial Instruments**

Carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate fair value because of the short-term nature of these instruments. Short-term investments comprise available-for-sale debt securities, which are carried at fair value. The Company believes that its borrowings bear interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value. The redeemable convertible preferred stock warrant liability is carried at fair value based on unobservable market inputs. The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy which establishes three levels of inputs that may be used to measure fair value (see Note 3).

**Concentration of Credit Risk, and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, short-term investments and accounts receivable to the extent of the amounts recorded on the balance sheet. The Company's cash is invested in one major financial institution in the United States. Deposits in this financial institution may exceed federally insured limits. The Company's cash equivalents are invested in money market funds.

The Company's accounts receivable are due from a variety of health care organizations in the United States. For the three and nine months ended September 30, 2022 and 2021, there were no customers that represented 10% or more of revenue. As of September 30, 2022 and December 31, 2021, no customer represented 10% or more of the Company's accounts receivable.

The Company is subject to certain risks, including that its devices may not be approved or cleared or continue to be approved or cleared for marketing by governmental authorities or be successfully marketed for expanded indications. There can be no assurance that the Company's products will achieve widespread adoption in the marketplace, nor can there be any assurance that existing devices or any future devices can be developed or manufactured at an acceptable cost and speed and with appropriate performance characteristics. The Company is also subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence on healthcare providers to prescribe initial implants and replacements, dependence upon third-party payors to provide adequate coverage and reimbursement, dependence on key personnel, single-source suppliers and vendors in connection with the manufacture of its products, concentration of Level 4 CECs and epileptologists, obtaining, maintaining, protecting, enforcing, and defending intellectual property rights and proprietary technology, product liability claims, legal proceedings, and compliance with government regulations.

The Company's medical devices require approvals or clearances from the U.S. Food and Drug Administration, or the FDA, or international regulatory agencies. In addition, in order to continue the Company's operations, compliance with various federal and state laws is required. If approvals or clearances were withdrawn by the FDA for the Company's current products or if such approvals or clearances were denied or delayed for future products, product updates, or expanded indications for use, it would have a material adverse impact on the Company.

**Leases**

The Company leases its facilities and meets the requirements to account for these leases as operating leases. For the three and nine months ended September 30, 2021, for facility leases that contain rent escalations or rent concession provisions, the Company recorded its lease expense during the lease term on a straight-line basis over the term of the lease. As of December 31, 2021, the Company recorded differences between the rent paid and the straight-line rent as a deferred rent liability. Leasehold improvements funded by landlord incentives or allowances were recorded as leasehold improvement assets and a corresponding deferred rent liability. The leasehold improvement asset is amortized over the lesser of the term of the lease or life of the asset.

Upon adoption of ASC 842, *Leases*, on January 1, 2022, the Company determined if an arrangement is a lease, or contains a lease, at inception. Operating leases are included in operating lease right-of-use, or ROU, assets, operating lease liability, and operating lease liability, net of current portion on the Company's condensed balance sheets.

ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment at commencement date in determining the present value of future payments. The ROU asset also includes any lease payments made to the lessor at or before the commencement date, minus lease incentives received, and initial direct costs incurred. The Company's 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. The Company elected certain practical expedients under ASC 842 which are: (i) to not record leases with an initial term of twelve months or less on the balance sheet; (ii) to combine the lease and non-lease components in determining the lease liabilities and right-of-use assets, and (iii) to carry forward prior conclusions about lease identification and classification.

**Government Programs**

In May 2021, the Company was awarded a grant by the National Institutes of Health, or NIH, to support research of thalamocortical responsive neurostimulation for the treatment of Lennox-Gastaut Syndrome, a type of epilepsy. The award was issued for a five-year period and has a total budget of over $9.3 million, which includes approximately $5.5 million in funding for subawards to third party academic epilepsy centers that are collaborating on the study and are subinvestigators on the study funded by NIH. The subawardees are determined by NIH. The Company's responsibility for the subawards is to submit the funding requests on behalf of the subawardees. The funding of subawards does not have any impact on the Company's condensed financial statements. Initially funding was approved for the first year beginning June 1, 2021 and provides for reimbursement of qualified direct and indirect expenses in the amount of $0.8 million, including $0.4 million for subawards. Approvals of funds for years two through five are subject to the completion of certain milestones. On July 30, 2022, the Company received funding approval for year two in the amount of $2.6 million, which includes $1.6 million for subawards.

For funds received under the NIH funding agreement, the Company recognizes a reduction in research and development expenses in an amount equal to the qualifying expenses incurred in each period up to the amount awarded by the NIH. Qualifying expenses incurred by the Company in advance of funding by the NIH are recorded within prepaid expenses and other current assets on the balance sheets. Through September 30, 2022, $0.5 million of qualifying expenses have been incurred and funded by the NIH related to the first and second year funding. As of September 30, 2022, the Company recorded prepaid expenses and other current assets of less than $0.1 million related to the second year funding.

**Net Loss per Share Attributable to Common Stockholders**

Basic net loss per common share 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 of 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, stock options, common stock subject to repurchase related to early exercise of stock options, and restricted stock units are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. The Company considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities, because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of the shares issued upon early exercise of stock options subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the

Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

**Recent Accounting Pronouncements**

***Recently Adopted Accounting Pronouncements***

In February 2016, the FASB issued ASU No. 2016-02 (Topic 842), *Leases*. ASU 2016-02 requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a ROU asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. This ASU provides a lessee with an option to not account for leases with a term of 12 months or less as leases in the scope of this ASU. This ASU also requires new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. This ASU should be applied through a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows entities to elect an optional transition method where entities may continue to apply the existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative effect adjustment in the period of adoption rather than in the earliest period presented. In June 2020, the FASB issued ASU 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*, which delayed the adoption dates for ASU 2016-02 for non-public entities to fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is allowed. The Company adopted Topic 842 effective January 1, 2022 using a modified retrospective method and did not restate comparative periods. The Company recognized ROU assets of $6.1 million and lease liabilities of $7.5 million for its operating leases as of January 1, 2022. In addition, the amount of the Company's deferred rent as of December 31, 2021 of $1.4 million was removed upon adoption. The adoption of these ASUs did not have any impact on the condensed statements of operations and comprehensive loss and condensed statements of cash flows. See Note 5 for more information related to the Company's lease obligations.

***Recent Accounting Pronouncements Not Yet Adopted***

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments- Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends existing guidance on the impairment of financial assets and adds an impairment model that is based on expected losses rather than incurred losses and requires an entity to recognize as an allowance its estimate of expected credit losses for its financial assets. An entity will apply this guidance through a cumulative-effect adjustment to retained earnings upon adoption (a modified-retrospective approach) while a prospective transition approach is required for debt securities for which an other-than-temporary impairment had been recognized before the effective date. For public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, adoption is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For SEC filers that are eligible to be smaller reporting companies and for all other entities, this ASU is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures, and does not expect the standard will have a material impact on the Company's financial statements and related disclosures.

**3. Fair Value Measurements**

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier

fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities.

The following table summarizes the Company's financial assets (cash equivalents, marketable securities and liabilities) at fair value as of September 30, 2022 (in thousands):

| | Fair Value as of September 30, 2022 | Basis for Fair Value Measurements (Level 1) | (Level 2) | (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Money market funds, included in cash and cash equivalents | $ 5,676 | $ 5,676 | $ — | $ — |
| Fixed income mutual funds, included in short-term investments | 79,724 | 79,724 | — | — |
| Total | $ 85,400 | $ 85,400 | $ — | $ — |

The following table summarizes the Company's financial assets (cash equivalents, marketable securities and liabilities) at fair value as of December 31, 2021 (in thousands):

| | Fair Value as of December 31, 2021 | Basis for Fair Value Measurements (Level 1) | (Level 2) | (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Money market funds, included in cash and cash equivalents | $ 16,498 | $ 16,498 | $ — | $ — |
| Fixed income mutual funds, included in short-term investments | 96,397 | 96,397 | — | — |
| Total | $ 112,895 | $ 112,895 | $ — | $ — |

There were no liabilities measured at fair value on a recurring and non-recurring basis as of September 30, 2022 and December 31, 2021.

The money market funds are highly liquid and primarily invest in short-term fixed income securities issued by the U.S. government and U.S. government agencies. The Company's available-for-sale investments comprise short-term investments in fixed income mutual funds, which primarily consist of debt securities issued by the U.S. government and U.S. government agencies and corporate bonds and notes.

The following is a summary of the Company's available-for-sale debt securities (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Cost basis | $ 81,058 | $ 96,702 |
| Unrealized loss | (1,334) | (305) |
| Fair value | $ 79,724 | $ 96,397 |

In determining the fair value of the redeemable convertible preferred stock warrant liability, the Company used the Black-Scholes option pricing model to estimate the fair value using unobservable inputs including the expected term, expected volatility, risk-free interest rate and dividend yield (see Note 8). There were no warrants outstanding for the purchase of redeemable convertible preferred stock as of September 30, 2022, as all such warrants were net exercised to shares of common stock upon the closing of the IPO.

The change in fair value of the redeemable convertible preferred stock warrant liability is summarized below (in thousands):

| | Redeemable Convertible Preferred Stock Warrant Liability |
|---|---|
| Fair value as of January 1, 2021 | $ 369 |
| Change in fair value included in other income (expense), net | 5,236 |
| Net exercise of redeemable convertible preferred stock warrants | (5,605) |
| Fair value as of September 30, 2021 | $ — |

## 4. Balance Sheet Components

### Inventory

Inventories consist of the following (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Raw materials | $ 3,171 | $ 2,232 |
| Work-in-process | 501 | 879 |
| Finished goods | 4,909 | 4,711 |
| Total | $ 8,581 | $ 7,822 |

### Property and Equipment, net

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

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Machinery, equipment, furniture and fixtures | $ 4,211 | $ 3,742 |
| Computer equipment and software | 2,952 | 2,916 |
| Leasehold improvements | 2,402 | 2,402 |
| | 9,565 | 9,060 |
| Less: Accumulated depreciation | (8,671) | (8,457) |
| Property and equipment, net | $ 894 | $ 603 |

Depreciation expense for the three months ended September 30, 2022 and 2021 was $0.1 million and $0.1 million, respectively. Depreciation expense for the nine months ended September 30, 2022 and 2021 was $0.2 million and $0.2 million, respectively.

**Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Payroll and related expenses | $ 5,991 | $ 6,547 |
| Inventory-raw materials | 377 | 251 |
| Professional fees | 365 | 109 |
| Deferred rent, current | — | 490 |
| Other | 817 | 526 |
| Total accrued liabilities | $ 7,550 | $ 7,923 |

## 5. Commitments and Contingencies

**Facility Lease**

In August 2011, the Company entered into a non-cancelable operating lease for combined office and manufacturing facilities in Mountain View, California. The lease was scheduled to expire in April 2019 and was amended in May 2018 to extend it through June 2024. In August 2022, the Company amended the lease to extend it through June 30, 2030. The second amendment contains a rent free period from September 1, 2022 through December 31, 2022. The Company has an option to extend the lease for a period of five years, commencing on July 1, 2030 and expiring on June 30, 2035. In conjunction with the original lease agreement, the Company obtained a letter of credit for $0.9 million in lieu of a security deposit. In May 2019, the letter of credit was amended and reduced to $0.7 million. In June 2021, the letter of credit was amended and further reduced to $0.2 million.

The terms of the facility lease provide for rental payments on a graduated scale; however, rent expense is recognized on a straight-line basis over the lease term. Rental payments range from $2.8 million to $3.3 million per year over the extended term of the lease. In April 2020, the Company amended the lease agreement to defer 50.0% of the rental payment for May and June 2020 of $0.3 million. The deferred rental payments accrued interest at an annual rate of 8.0% starting from October 1, 2020 and were paid in three equal monthly installments commencing on April 1, 2021.

Rent expense for the three and nine months ended September 30, 2021 was $0.7 million and $2.1 million, respectively. As of December 31, 2021, $1.4 million was recorded as deferred rent liability.

The Company’s future minimum lease payments under the non-cancellable operating lease as of December 31, 2021 were as follows (in thousands):

| | December 31, 2021 |
|---|---|
| 2022 | $ 3,172 |
| 2023 | 3,267 |
| 2024 | 1,666 |
| Total | $ 8,105 |

The maturities of operating lease liabilities as of September 30, 2022 are as follows (in thousands):

| | September 30, 2022 |
|---|---|
| 2022 (remaining three months) | $ — |
| 2023 | 2,773 |
| 2024 | 2,857 |
| 2025 | 2,942 |
| 2026 | 3,031 |
| Thereafter | 11,354 |
| Total undiscounted lease payments | 22,957 |
| Less: imputed interest | 6,571 |
| Total operating lease liability | 16,386 |
| Less: current portion | 692 |
| Operating lease liability, net of current portion | $ 15,694 |

Operating lease cost was $0.7 million and $2.0 million for the three and nine months ended September 30, 2022, respectively. As of September 30, 2022, the remaining term for the operating lease in Mountain View, California was 7.8 years, and the discount rate used to measure the lease liability for such operating lease upon recognition was 8.5%.

During the nine months ended September 30, 2022, cash paid for amounts included in operating lease liabilities of $2.1 million was included in cash flows from operating activities on the condensed statements of cash flows.

**Distribution Agreement**

In August 2022, the Company entered into an Exclusive Distribution Agreement, or the Distribution Agreement, with DIXI Medical USA Corp, or DIXI Medical, pursuant to which the Company becomes the exclusive U.S. distributor of DIXI Medical's product line. To maintain the exclusive distributor rights, the Company is committed to purchase a minimum of $2.4 million of DIXI Medical's products during the first twelve months following October 1, 2022, and increase the purchase minimum by 10% for each of the two subsequent years.

**Indemnifications**

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. The Company may, from time to time, be subject to claims or be required to defend actions related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director or officer is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as the director or officer may be subject to any proceeding arising out of acts or omissions of such individual in such capacity. The maximum amount of potential future indemnification is unlimited. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of September 30, 2022 and December 31, 2021.

**Contingencies**

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company determined that no accrual related to contingencies was required as of September 30, 2022 and December 31, 2021.

**Legal Proceedings**

The Company is, and from time to time may become, involved in legal proceedings. The Company may also pursue litigation to assert its legal rights and such litigation may be costly and divert the efforts and attention of its management and technical personnel which could adversely affect its business. Due to the uncertainty of litigation and depending on the amount and the timing, an unfavorable resolution of some or all of such matters may materially affect our business, results of operations, financial position, or cash flows. The Company regularly evaluates current information to determine whether any accruals should be adjusted and whether new accruals are required. Such accruals, if any, reflect the estimable and probable costs that the Company may incur from the outcomes of its legal proceedings. Actual claims could settle or be adjudicated against the Company in the future for materially different amounts than the Company has accrued due to the inherently unpredictable nature of litigation. Legal costs are expensed as incurred. The Company believes it has recorded adequate provisions for any such lawsuits and claims as of September 30, 2022. The provisions are immaterial and are recorded within selling, general and administrative expenses. The nature of the loss contingencies relating to claims that have been asserted against us are described below.

On April 20, 2021, the Company received correspondence from the United States Department of Treasury regarding an inquiry into a matter that may fall under the jurisdiction of the Committee on Foreign Investment in the United States, or CFIUS. While the Company believes that its RNS System is not a critical technology for which CFIUS would have jurisdiction and does not pose a national security risk, the Company is cooperating fully with CFIUS on the matter.

Additionally, on October 18, 2021, three stockholders of the Company, James Jacoby, George Vachtsevanos, and Javier Echauz, or together with Company, the Parties, filed a complaint in the United States District Court for the Northern District of California, or the Court, entitled *James Jacoby et al. v. NeuroPace, Inc., et al.*, Case No. 3:21-cv-8136, against the Company and its board of directors. The complaint alleged various claims related to the Company's reverse stock splits and seeks, among other relief, damages and attorney's fees. The complaint was amended on December 28, 2021 to name additional defendants. On August 8, 2022, the Parties entered into a confidential settlement agreement, which contains, among other things, a mutual release of claims and no admission of liability by defendants. On August 9, 2022, the Parties filed a stipulation of dismissal with prejudice, which was entered by the Court on August 9, 2022. Although the Company has agreed to settle these claims, it continues to believe there was no merit to the stockholders' allegations. The Company recorded an immaterial expense related to this complaint.

**6. Debt**

**2020 Term Loan**

In September 2020, the Company entered into a Term Loan Agreement with CRG Partners IV L.P. and its affiliates for total borrowings of up to $60.0 million, or the Term Loan, and borrowed $50.0 million. The remaining $10.0 million of the Term Loan was available to the Company for borrowing until March 31, 2022 if the Company achieved a revenue-based milestone in 2021. The revenue-based milestone was not achieved, and the remaining $10.0 million of the Term Loan expired without being drawn.

The Term Loan bears interest at a rate of 12.5% per year. Payments under the Term Loan are made quarterly with payment dates fixed at the end of each calendar quarter. Through December 31, 2020, the Company had the option to pay the entire interest paid-in-kind, or PIK, by increasing the principal of the Term Loan. From January 1, 2021 through June 30, 2025, the Company has the option to pay interest as follows: 7.5% per annum paid in cash and 5.0% per annum PIK by increasing the principal of the Term Loan. For each payment date from April 1, 2022 through September 30, 2022, the Company elected the PIK option, increasing the principal of the Term Loan by $1.3 million.

The Term Loan was interest-only through September 30, 2023, which could be extended through September 30, 2025 at the Company's option if the Company completed its IPO on or prior September 30, 2023. In connection with closing the IPO, the Company extended the interest-only period to September 30, 2025. Following the interest-only period, principal payment is due in one installment on September 30, 2025. The Term Loan includes a fee upon

repayment of the loan equal to 10% of the aggregate principal amount being prepaid or repaid, or the backend fee. As of September 30, 2022, the Term Loan had an annual effective interest rate of 15.67% per year.

The Term Loan is collateralized by substantially all of the Company's assets. The Term Loan Agreement contains customary representations and warranties, covenants, events of default and termination provisions. The financial covenants require that the Company achieve minimum annual revenue thresholds commencing in 2021 and maintain a minimum balance of cash and cash equivalents (see Note 1). In March 2022, the Term Loan was amended to reduce the minimum annual net revenue covenant to $43.0 million for the year ended December 31, 2022.

The Company paid $1.0 million in fees to the lender and third parties which is reflected as a discount on the loan and is being accreted over the life of the loan using the effective interest method. Also, the Company issued warrants to the lender for a total of 346,823 shares of Series B' redeemable convertible preferred stock. The warrants had a fair value of $0.6 million as of the issuance date, which was accounted for as debt issuance costs (see Note 8).

During the three months ended September 30, 2022 and 2021, the Company recorded interest expense related to debt discount and debt issuance costs of the Term Loan of $0.1 million and $0.1 million, respectively. During the nine months ended September 30, 2022 and 2021, the Company recorded interest expense related to debt discount and debt issuance costs of the Term Loan of $0.2 million and $0.2 million, respectively.

Interest expense on the Term Loan was $1.9 million and $1.9 million during the three months ended September 30, 2022 and 2021, respectively. Interest expense on the Term Loan was $5.6 million and $5.5 million during the nine months ended September 30, 2022 and 2021, respectively.

As of September 30, 2022, future minimum payments for the Term Loan are as follows (in thousands):

| | Term Loan |
|---|---|
| 2022 (remaining three months) | $ 1,638 |
| 2023 | 6,499 |
| 2024 | 6,517 |
| 2025 | 61,268 |
| Total | 75,922 |
| Less: Unamortized debt discount and issuance cost | (970) |
| Less: Unaccreted backend fee | (3,483) |
| Less: Interest | (19,515) |
| Term Loan | $ 51,954 |

**Paycheck Protection Program**

In April 2020, the Company received $4.0 million from a federal Small Business Administration loan under the Paycheck Protection Program, or the PPP Loan. The note bore interest at 1.0% per year on the outstanding principal amount and had a maturity date 24 months from the date of the note. No payments were due for the six-month period beginning on the date of the note. Payments of principal and interest were due over the following 18 months. The Small Business Administration modified the PPP Loan such that monthly payments of principal and interest were due from September 2021 through April 2022. In April 2021, the Company repaid its entire obligation under the PPP Loan amounting to $4.1 million, including principal of $4.0 million and interest of less than $0.1 million, using the proceeds from its IPO.

## 7. Redeemable Convertible Preferred Stock

On April 26, 2021, upon the closing of the Company's IPO, all outstanding redeemable convertible preferred stock automatically converted into 16,614,178 shares of common stock. There was no issued and outstanding redeemable convertible preferred stock as of September 30, 2022 and December 31, 2021.

**8. Redeemable Convertible Preferred Stock Warrant Liability**

On September 24, 2020, in connection with entering into the Term Loan Agreement, the Company issued CRG Partners IV L.P. and its affiliates warrants to purchase 346,823 shares of Series B' redeemable convertible preferred stock at an exercise price of $6.51339 per share, or the Series B' Warrants, which was accounted as debt issuance costs.

The Series B' Warrants would terminate at the earlier of the ten-year anniversary from the issuance date, the closing of the Company's IPO or liquidation of the Company. These warrants had a net exercise provision under which their holders could, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of the Company's stock at the time of exercise of the warrants after deduction of the aggregate exercise price. The Series B' Warrants contained provisions for adjustment of the exercise price and number of shares issuable upon the exercise of warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications, and consolidations.

The fair value of the Series B' Warrants on the date of issuance of $0.6 million was recorded as a debt discount. Upon the closing of the IPO, the Series B' Warrants were net exercised to 213,941 shares of Series B' redeemable convertible preferred stock and subsequently converted into common stock on a one-to-one basis. Upon the closing of the IPO, the Company remeasured the Series B' Warrants to fair value of $5.6 million, which was the intrinsic value of net exercised common stock, as according to the Series B' Warrant agreements the Series B' Warrants were to be automatically exercised upon the IPO and the expected term of the Series B' Warrants was zero immediately before the closing of the IPO. Upon the closing of the IPO, the redeemable convertible preferred stock warrant liability was reclassified to additional paid-in capital.

The change in fair value of $0 and $(5.2) million during the three and nine months ended September 30, 2021 was recorded as a component of other income (expense), net in the condensed statements of operations and comprehensive loss.

**9. Common Stock**

The Company's Amended and Restated Certificate of Incorporation authorizes the Company to issue 200,000,000 shares of $0.001 par value common stock.

The holders of common stock are entitled to receive dividends whenever funds and assets are legally available and when declared by the Board of Directors. As of September 30, 2022 and December 31, 2021, no dividends had been declared.

As of September 30, 2022 and December 31, 2021, the Company had reserved common stock for future issuance as follows:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Shares available for future grant under the 2021 Plan | 1,383,132 | 2,132,750 |
| Outstanding options under the 2021 Plan | 3,506,756 | 3,038,970 |
| Outstanding restricted stock units under the 2021 Plan | 1,822,209 | 596,085 |
| Common stock available for ESPP | 567,481 | 470,169 |
| Total | 7,279,578 | 6,237,974 |

**10. Stock-Based Incentive Compensation Plans**

A summary of shares available for grant under the Company's 2021 Equity Incentive Plan, or the 2021 Plan, is as follows:

| | Shares Available for Grant |
|---|---|
| Shares available for grant as of January 1, 2022 | 2,132,750 |
| Authorized | 1,222,649 |
| Granted/Awarded | (2,219,220) |
| Cancelled | 239,914 |
| Withheld for taxes | 7,039 |
| Shares available for grant as of September 30, 2022 | 1,383,132 |

A summary of stock option activity for the nine months ended September 30, 2022 is set forth below:

| | Options Outstanding | | |
|---|---|---|---|
| | Number of Shares | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (in Years) |
| Balances as of January 1, 2022 | 3,038,970 | $ 2.61 | 8.83 |
| Granted | 690,218 | $ 7.83 | |
| Exercised | (129,200) | $ 0.03 | |
| Cancelled | (93,232) | $ 7.69 | |
| Balances at September 30, 2022 | 3,506,756 | $ 3.59 | 8.36 |
| Vested and exercisable at September 30, 2022 | 1,518,126 | $ 1.94 | 8.03 |
| Vested and expected to vest at September 30, 2022 | 3,506,756 | $ 3.59 | 8.36 |

**Early Exercise of Stock Options**

The terms of the Company's 2020 Stock Plan, or the 2020 Plan, and the 2021 Plan, permit the exercise of options granted under the plans prior to vesting, subject to required approvals. The shares of common stock issued from the early exercise of unvested stock options are restricted and continue to vest over the original implied service period. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employees and non-employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. The cash received in exchange for exercised and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock options in accrued liabilities on the accompanying balance sheet and will be transferred into common stock and additional paid-in capital as the shares vest. As of September 30, 2022 and December 31, 2021, there were 111,527 and 174,171 shares of common stock, respectively, issued pursuant to early exercised options and subject to repurchase.

**Employee Stock Purchase Plan**

In April 2021, the Company adopted the 2021 Employee Stock Purchase Plan, or ESPP. The Company allows eligible employees to purchase shares of the Company's common stock through payroll deductions at a price equal to 85% of the lesser of the fair market value of the stock as of the first date or the ending date of each offering period, which is typically six months. There were 580,000 shares of common stock initially reserved for issuance under the ESPP. In January 2022, the number of shares of common stock available for issuance under the ESPP was increased by 244,529 shares as a result of the automatic evergreen increase provision in the ESPP. The ESPP offering periods and purchase periods are determined by the Company's board of directors, or the Board.

The first offering period was for 0.6 years beginning May 20, 2021 through December 6, 2021. The Company issued 109,831 shares under the ESPP for the year ended December 31, 2021. The second offering period was for six months beginning December 7, 2021 through June 6, 2022. The Company issued 147,217 shares under the ESPP for the three months ended June 30, 2022. As of September 30, 2022, 567,481 shares under the ESPP remain

available for purchase. The Board authorized a new offering period of six months, which began on June 7, 2022 and runs through December 6, 2022.

**Restricted Stock Units**

Activity with respect to restricted stock units was as follows:

| | Number of Shares Underlying Outstanding Restricted Stock Units | Weighted Average Grant Date Fair Value |
|---|---|---|
| Unvested, January 1, 2022 | 596,085 | $ 22.06 |
| Granted | 1,529,002 | $ 7.89 |
| Vested | (156,196) | $ 23.52 |
| Cancelled | (146,682) | $ 14.68 |
| Unvested, September 30, 2022 | 1,822,209 | $ 10.64 |

The Company recognized stock-based compensation as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Cost of goods sold | $ 129 | $ 93 | $ 402 | $ 134 |
| Research and development | 563 | 348 | 1,751 | 694 |
| Selling, general and administrative | 1,490 | 666 | 4,120 | 1,584 |
| Total stock-based compensation | $ 2,182 | $ 1,107 | $ 6,273 | $ 2,412 |

The above stock-based compensation expense related to the following equity-based awards (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Stock options and restricted stock units | $ 2,054 | $ 714 | $ 5,897 | $ 1,839 |
| ESPP | 128 | 393 | 376 | 573 |
| Total stock-based compensation | $ 2,182 | $ 1,107 | $ 6,273 | $ 2,412 |

As of September 30, 2022, the total unrecognized stock-based compensation expense related to unvested stock options and restricted stock units was $22.9 million, which will be amortized on a straight-line basis over a weighted average remaining period of 3.0 years.

As of September 30, 2022, the Company had unrecognized stock-based compensation expense relating to the ESPP awards of approximately $0.1 million, which is expected to be recognized over a weighted-average period of 0.2 years.

**11. Income Taxes**

The Company did not record a federal or state income tax provision or benefit for the three and nine months ended September 30, 2022 and 2021 as it has incurred net losses since inception. In addition, the net deferred tax assets generated from net operating losses are fully offset by a valuation allowance as the Company believes it is not more likely than not that the benefit will be realized.

The Company accounts for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return. There has been no changes in the estimated uncertain tax benefits recorded as of December 31, 2021.

**12. Net Loss per Share Attributable to Common Stockholders**

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except for share and per share amounts):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| **Numerator:** | | | | |
| Net loss attributable to common stockholders | $ (11,785) | $ (8,083) | $ (35,936) | $ (25,387) |
| **Denominator:** | | | | |
| Weighted-average common stock outstanding used to compute basic and diluted net loss per share | 24,728,701 | 24,101,399 | 24,514,820 | 14,061,958 |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.48) | $ (0.34) | $ (1.47) | $ (1.81) |

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss, in common stock equivalent shares:

| | As of September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Options to purchase common stock | 3,506,756 | 3,089,821 |
| Unvested early exercised common stock options | 111,527 | 192,741 |
| Shares committed under ESPP | 127,451 | 57,514 |
| Unvested restricted stock units | 1,822,209 | 552,304 |
| Total Shares | 5,567,943 | 3,892,380 |

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our condensed financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, which are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors," under Part II, Item 1A of this report and those discussed in our other disclosures and filings.*

### Overview

We are a commercial-stage medical device company focused on transforming the lives of people living with epilepsy by reducing or eliminating the occurrence of debilitating seizures. Our novel and differentiated RNS System is the first and only commercially available, brain-responsive neuromodulation system that delivers personalized, real-time treatment at the seizure source. By continuously monitoring the brain's electrical activity, recognizing patient-specific abnormal electrical patterns, and responding in real time with imperceptible electrical pulses to prevent seizures, our RNS System delivers the precise amount of therapy when and where it is needed and provides exceptional clinical outcomes with approximately three minutes of stimulation on average per day. Our RNS System is also the only commercially available device that records continuous brain activity data and allows clinicians to monitor patients not only in person, but also remotely, in order to make more informed treatment decisions, thus optimizing patient care. We believe the therapeutic advantages of our RNS System, combined with the insights obtained from our extensive brain data set, offer a significant leap forward in epilepsy treatment.

Our RNS System is currently indicated in the United States for use in adult epilepsy patients, meaning patients who are 18 years of age or older, with drug-resistant focal epilepsy. As of September 30, 2022, over 4,000 epilepsy patients have received our RNS System. We believe our compelling body of long-term clinical data, demonstrating continuous improvement in outcomes over time, will support the continued adoption of our RNS System among the approximately 575,000 adults in the United States with drug-resistant focal epilepsy. We continue seeking indication expansion to, over time, more broadly reach the entire approximately 1.2 million drug-resistant epilepsy patients in the United States and may additionally seek to expand our operations to reach the approximately 16.5 million drug-resistant epilepsy patients globally.

Our commercial efforts are focused on the comprehensive epilepsy centers, or Level 4 CECs, that facilitate appropriate care for drug-resistant epilepsy patients, including procedures for implantation of epilepsy neuromodulation devices such as our RNS System. While most drug-resistant epilepsy patients begin their care at physician offices or community hospitals, we estimate that approximately 24,000 adult drug-resistant focal epilepsy patients are treated in Level 4 CECs in the United States each year. We estimate that this patient pool represents an annual core market opportunity of approximately $1.1 billion for initial RNS System implants, and we expect that it will continue to grow as the number of Level 4 CECs and the number of epilepsy specialists increase, as more patients are referred to these CECs, and as more care for RNS-implanted patients can happen outside of the Level 4 CECs. In addition, the sale of replacement neuromodulation devices when the battery in our RNS neurostimulator approaches end of service provides a recurring revenue stream that is additive to our current $1.1 billion annual market opportunity for initial implants.

We received Premarket Approval, or PMA, from the FDA for our RNS System in late 2013 and began the commercial rollout of our RNS System in early 2014. We market our RNS System in the United States through a direct sales organization primarily to the epileptologists and neurosurgeons who respectively prescribe and implant neuromodulation devices in the approximately 200 Level 4 CECs in the United States. We have established a significant account base at these Level 4 CECs. Given the concentrated and underpenetrated nature of our target market, we believe that through our expanded sales force, there is a significant opportunity to efficiently grow our account base, drive higher utilization within these centers, and expand our referral channel to increase the number of drug-resistant patients referred to Level 4 CECs.

The implant procedure for our RNS System and the ongoing patient treatment provided by clinicians, including monitoring and programming, are reimbursed under well-established physician and hospital codes. In addition, we believe that our RNS System is currently the only neuromodulation system for epilepsy with reimbursement available for periodic in-person or remote review of brain activity data. Given the relatively young average age of our patient population, our payor mix has historically been more heavily weighted towards commercial payors. As of September 30, 2022, commercial payors have written positive coverage policies that address over 200 million covered lives in the United States. Medicare and Medicaid also routinely provide coverage for implantation of our RNS System and follow-up care. Based on our experience, less than 1% of potential RNS System patients have been unable to undergo an implant procedure with our RNS System due to lack of payor coverage. We believe the established, differentiated, and favorable reimbursement paradigm for our RNS System will continue to support its broad commercial adoption.

We currently manufacture our RNS System at and distribute all of our products from our approximately 53,000 square foot facility in Mountain View, California. This facility provides approximately 20,000 square feet of space for our production and distribution operations, including manufacturing, quality control and storage. We believe our existing facility will be sufficient to meet our current and near-term manufacturing needs.

Since our inception, we have generated significant losses. To date, we have financed our operations primarily through the sale of equity securities, debt financing arrangements and sales of our products. As of September 30, 2022, we had an accumulated deficit of $459.7 million, cash, cash equivalents and short-term marketable debt securities of $85.4 million, and $52.0 million of outstanding term loans, net of debt discount and issuance costs.

On April 21, 2021, we completed our initial public offering of our common stock, or IPO, in which we issued and sold an aggregate of 6,900,000 shares of common stock (inclusive of 900,000 shares pursuant to the exercise by the underwriters of their option) at a price of $17.00 per share for aggregate cash proceeds of approximately $105.5 million, net of underwriting discounts and commissions and offering costs. The sale and issuance of 6,900,000 shares in the IPO closed on April 26, 2021. Upon the closing of the IPO, all outstanding shares of redeemable convertible preferred stock automatically converted into 16,614,178 shares of common stock. Subsequent to the closing of the IPO, there were no shares of redeemable convertible preferred stock outstanding.

We have invested heavily and expect to continue to invest in research and development and commercial activities. Our research and development activities include clinical studies to demonstrate the safety and efficacy of our RNS System and to obtain, as well as retain, FDA approval. We intend to continue making significant investments in research and development, clinical studies and regulatory affairs to support ongoing and future regulatory submissions for retaining and expanding indications of our RNS System, including to adolescent patients, ages 12-17, and drug-resistant generalized epilepsy patients, support continuous improvements to our RNS System, and develop future products that address neurological disorders. We have also made significant investments in building our field commercial team and intend to make significant investments in sales and marketing efforts in the future, including initiatives to drive awareness and expand our referral channel to increase the number of drug-resistant epilepsy patients referred to Level 4 CECs. Moreover, we expect to continue to incur additional expenses associated with operating as a public company. We may in the future seek to acquire or invest in additional businesses, products, or technologies that we believe could complement or enhance our products, enhance our technical capabilities or otherwise offer growth opportunities, although we currently have no agreements or understandings with respect to any such acquisitions or investments. Because of these and other factors, we expect to continue to incur net losses and negative cash flows for the next several years. We may require additional funding to support operations and pay our obligations or may opportunistically seek to raise additional capital, which may include future equity or debt financings.

We believe our existing cash, cash equivalents and short-term investments will allow us to continue our operations for at least the next 12 months.

**Recent Developments**

***Impact of the COVID-19 Pandemic***

Since it was reported to have surfaced in December 2019, the SARS-CoV-2 strain of coronavirus, or COVID-19, has spread across the world, being declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have been significant and governments around the world, including in the United States, have implemented severe travel restrictions, social distancing requirements, quarantines, stay-at-home orders and other significant restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge and is affecting hospitals, physicians, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. and world economy and in financial markets.

The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by decreasing and delaying procedures performed to implant our RNS System, delaying and decreasing epilepsy diagnostic evaluations at epilepsy monitoring units, or EMUs, as well as creating hospital staffing shortages and periodic increased vacation demand as a result of loosening travel restrictions, and we expect the pandemic will continue to negatively impact our business, financial condition and results of operations. Beginning in March 2020 and continuing into 2022, our net sales have been negatively impacted by the COVID-19 pandemic as hospitals delay or cancel elective procedures, including because of staffing shortages and patients fearing potential exposure. Many state and local governments in the U.S. have issued periodic orders that temporarily preclude elective procedures in order to conserve scarce health system resources in view of the pandemic and to protect patient health. The decreases in hospital admission rates and elective surgeries have reduced the demand for elective procedures, including implantation of our RNS System. In addition, hospitals delayed or cancelled admissions for epilepsy diagnostic evaluations which we believe has reduced and will continue to temporarily reduce our patient pipeline.

In response to the COVID-19 pandemic, we have made investments to implement a variety of measures intended to help us manage its impact while maintaining business continuity to support our customers and patients. These measures include:

- Establishing safety protocols, facility enhancements, and work-from-home strategies to protect our employees;
- Ensuring that our manufacturing and supply chain operations remain intact and operational;
- Keeping our workforce intact, including our experienced and specialized U.S. sales and clinical support team;
- Developing new methods of supporting physicians remotely in their use of our RNS System;
- Implementing virtual physician training programs to support opening new accounts with minimal in person interaction;
- Continuing our physician education programs and direct-to-patient marketing efforts through social media and other virtual forums; and
- Increasing our capital resources through the completion of our IPO in April 2021.

While our hospital customers began to gradually perform elective epilepsy procedures again during the second half of 2020, we saw another reduction in these procedures in late 2020 and during parts of 2021 and 2022. Our business was negatively impacted in the third quarter of 2021 due to the rise in COVID-19 Delta variant cases, increased vacation demand and hospital staffing shortages and in the fourth quarter of 2021 due to the rise in COVID-19 Omicron variant cases and ongoing hospital staffing shortages. Continued surges in cases as a result of Omicron variants have had a significant negative impact on our business due to limits on elective procedures and hospital staffing shortages. Our business was negatively impacted in the second quarter of 2022 due to a reduced

patient pipeline resulting from delayed or cancelled EMU admissions for epilepsy diagnostic evaluations in prior quarters and from ongoing hospital staffing shortages.

We believe the challenges resulting from COVID-19 will likely continue for the duration of the pandemic, which is uncertain, and will continue to impact our revenue and negatively impact our business, financial condition and results of operations. While our business grew in 2021, we continue to experience variability in RNS procedures, largely coinciding with periodic spikes in COVID-19 cases. Given the dramatic increase in COVID-19 infections in the first half of 2022, we cannot provide assurance that we will not experience additional negative impacts associated with COVID-19, which could be significant. We believe that we may see fluctuations in RNS System procedures as the impact of COVID-19 continues. In addition, due to the pandemic, our patient pipeline may continue to be reduced temporarily due to a delay in the diagnostic evaluations that are used to identify appropriate patients for our RNS System. Further, once the pandemic subsides, there may be a substantial backlog of EMU admissions and of procedures to be performed at hospitals for a variety of medical conditions. As a result, patients seeking treatment with our RNS System may have to navigate limited provider capacity. We believe this limited EMU and hospital capacity could have a significant adverse effect on our business, financial condition and results of operations throughout the remainder of and following the end of the pandemic. We experienced unusual seasonality in parts of 2021 and may experience seasonality in the future as certain pandemic restrictions are relaxed and physicians and patients take vacations, resulting in a reduction in RNS procedures. Additionally, hospitals continue to experience staffing shortages and may experience them in future, also resulting in a reduction in RNS procedures. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and its variants and the actions to contain the spread of COVID-19 and its variants or treat its impact, among others.

Our financial statements reflect judgments and estimates that could change in the future as a result of the COVID-19 pandemic.

***DIXI Distribution Agreement***

In August 2022, we entered into an Exclusive Distribution Agreement, or the Distribution Agreement, with DIXI Medical USA Corp. pursuant to which we became the exclusive U.S. distributor of DIXI Medical's product line beginning in October 2022. DIXI Medical is a subsidiary of a European company that pioneered the development of stereo electroencephalography, or Stereo EEG, electrodes. These electrodes are used in the epilepsy monitoring units of comprehensive epilepsy centers to determine where epileptic seizures originate. In addition to providing us with an incremental revenue stream, the DIXI Medical partnership will provide us with improved visibility of patients moving through the epilepsy monitoring units, many of whom may be candidates for the RNS System. This synergistic partnership leverages our field organization that is already calling on the same customers and supports our objective to engage earlier in the diagnostic and therapy selection process. DIXI Medical will supply us with ongoing commercial support and will supply us with DIXI Medical products as ordered by us.

In consideration for DIXI Medical's ongoing commercial support, we will pay DIXI Medical a $2.0 million cash payment in the fourth quarter of 2022 and a $1.25 million cash payment in each of the fourth quarters of 2023 and 2024, for a total of $4.5 million. We expect to recognize incremental operating expenses of approximately $1.0 million in the fourth quarter of 2022 primarily associated with the distribution launch. We will incur ongoing expenses in connection with our performance under the Distribution Agreement, although we expect that ongoing quarterly expenses will be less than in the fourth quarter of 2022.

**Factors Affecting our Performance**

We believe there are several important factors that have impacted and that we expect will continue to impact our business and results of operations. These factors include:

***Clinician, Hospital and Patient Awareness and Acceptance of Our RNS System***

Our goal is to establish our RNS System as a standard of care for drug-resistant epilepsy. We intend to continue to promote awareness of our RNS System within existing and new accounts through additional investments in

training and education of clinicians, epilepsy centers, hospitals and patients on the clinical benefits of our RNS System for the treatment of drug-resistant epilepsy. In addition, we intend to publish additional clinical data in scientific journals and to continue presenting at medical conferences. We plan to continue building patient awareness through direct-to-patient marketing initiatives, which include advertising, social media and online education. We also intend to continue supporting patient and referring clinician outreach efforts to help increase the number of appropriate patients with drug-resistant epilepsy being treated at Level 4 CECs. These efforts require significant investment by our marketing and sales organization.

***Our Ability to Retain Our Experienced Commercial Team and Increase its Productivity***

We have made significant investments in, and will continue to invest in, recruiting, training and retaining our experienced and specialized direct sales team, which includes Therapy Consultants and Field Clinical Engineers. Significant education and training is required for our team to achieve the level of technical competency with our products that is expected by clinicians and to gain experience building demand for our RNS System. Upon completion of initial training, our personnel typically require time in the field to grow their network of accounts, build relationships with clinicians and increase their productivity to the levels we expect. We believe successfully training, developing and retaining our Therapy Consultants and Field Clinical Engineers will be required to achieve growth. In addition, the loss of any productive sales personnel would have a negative impact on our ability to grow our business.

***Competition***

Our industry is highly competitive and subject to rapid change from the introduction of new products and technologies and the marketing activities of industry participants. There are two primary treatment alternatives for adults with drug-resistant epilepsy: (i) an ablative or resective surgery; and (ii) implantation of a neuromodulation device. Within neuromodulation, we currently compete with two manufacturers of neuromodulation devices. These companies have longer operating histories, significantly greater resources and name recognition, and established relationships with physicians and hospitals that treat patients with epilepsy. In addition to competing for market share, we also compete against these companies for personnel, including qualified sales and other personnel that are necessary to grow our business.

***Leveraging Our Manufacturing Capacity to Further Improve Our Gross Margin***

With our current operating model and infrastructure, we believe that we have the capacity to significantly increase our manufacturing production. If we grow our revenue and sell more RNS Systems, our fixed manufacturing costs will be spread over more units, which we believe will reduce our manufacturing costs on a per-unit basis and in turn improve our gross margin. In addition, we intend to continue investing in manufacturing efficiencies in order to reduce our overall manufacturing costs. However, other factors will continue to impact our gross margin such as the cost of materials, components and subassemblies, pricing, procedure mix, and geographic sales mix to the extent that we commercialize our RNS System outside of the United States.

***Investing in Research and Development, Including Clinical Studies, to Expand Our Addressable Market***

We intend to continue investing in clinical studies and existing and next generation technologies to further improve our RNS System and clinical outcomes, enhance the patient and provider experience and broaden the patient population that can be treated with our RNS System. In addition, we are continuing to leverage our extensive database of intracranial electroencephalogram, or iEEG, data and our advanced data analysis capabilities to equip clinicians with the data they need to establish optimal program settings for each patient.

While research and development and clinical studies are time consuming and costly, we believe that a pipeline of product enhancements and new products that improve efficacy, safety and ease of use is important for supporting increased adoption of our RNS System.

***Change in Product Mix***

We derive revenue from sales of our RNS System to hospital facilities both for initial RNS System implant procedures and for replacement procedures when our implanted devices reach end of service. We launched our current neurostimulator model in 2018. The FDA recently approved labeling changes indicating that this device has an average battery life of nearly eleven years, an increase from the previous assumption of eight years. We expect that our revenue from replacement procedures will decrease over the next few years as a result of the extended replacement cycle of the newer device. In addition, a change in procedure mix between initial and replacement procedures may have a negative impact on our gross margin. Beginning in the fourth quarter, we expect to derive revenue from sales of DIXI Medical products. A change in product mix between sales of our RNS System and DIXI Medical products may have a negative impact on our gross margin.

**Components of Our Results of Operations**

***Revenue***

We derive substantially all our revenue from sales of our RNS System to hospital facilities (typically Level 4 CECs) that implant our RNS System. We currently deliver our RNS System to a hospital on the date of the scheduled procedure. There is no commitment to purchase our RNS System until the delivery of the product, as the procedure may be canceled at any time.

Our revenue fluctuates primarily based on the volume of procedures performed and the procedure mix between initial and replacement implants. Our revenue also fluctuates and in the future will continue to fluctuate from quarter-to-quarter due to a variety of factors, including the success of our sales force in expanding adoption of our RNS System in new accounts and the number of physicians who are aware of and prescribe our RNS System.

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

Cost of goods sold consists primarily of costs related to materials, components and subassemblies, personnel-related expenses for our manufacturing and quality assurance employees, including stock-based compensation, manufacturing overhead, charges for excess, obsolete and non-sellable inventories, and royalties. Overhead costs include the cost of quality assurance, testing, material procurement, inventory control, operations supervision and management personnel, an allocation of facilities and information technology expenses, including rent and utilities, and equipment depreciation. Cost of goods sold also includes certain direct costs such as those incurred for shipping our RNS System. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect cost of goods sold to increase in absolute dollars as more of our RNS Systems are sold.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily by our manufacturing costs and pricing. Our gross margin may increase over the long term to the extent our production volume increases as our fixed manufacturing costs would be spread over a larger number of units, thereby reducing our per-unit manufacturing costs. We expect our gross margin to fluctuate from period to period, however, based upon the factors described above.

***Operating Expenses***

Our operating expenses consist of research and development costs and selling, general and administrative costs.

*Research and Development Expenses*

Our research and development activities primarily consist of engineering and research programs associated with our products under development and clinical studies. Research and development expenses include personnel-related costs for our research and development employees, including stock-based compensation, and expenses related to consulting services, clinical trials, regulatory activities, prototyping, testing, materials and supplies, and allocated overhead including facilities and information technology expenses. Our clinical trial expenses include costs associated with clinical trial design, clinical trial site development and study costs, data management costs, related

travel expenses, the cost of products used for clinical activities, and costs associated with our regulatory compliance. We expense research and development costs as they are incurred. We expect our research and development expenses to increase in absolute dollars as we continue to develop new product offerings and product enhancements and conduct studies for expanded indications for use.

*Selling, General and Administrative Expenses*

Our selling, general and administrative expenses consist primarily of personnel-related costs for our sales and marketing employees, including stock-based compensation and sales-based variable compensation, travel expenses, consulting, public relations costs, direct marketing, customer training, trade show and promotional expenses and allocated facility and information technology expenses, and for administrative personnel that support our general operations such as executive management and information technology, finance, accounting, customer services, human resources and legal personnel. We expense sales variable compensation when revenue related to the underlying sale is recognized. Selling, general and administrative expenses also include costs attributable to professional fees for legal, accounting and tax services, insurance and recruiting fees.

We intend to continue to increase our sales and marketing spending to support increased adoption of our RNS System. We expect our sales and marketing expenses to increase in absolute dollars as we hire additional personnel and add programs in order to more fully penetrate the market opportunity. We expect our administrative expenses, including stock-based compensation expense, to increase as we increase our headcount and expand our systems to support our operations as a public company. Additionally, we anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with being a public company, compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, and director and officer insurance premiums. Our selling, general and administrative expenses may fluctuate from period to period as we continue to grow.

*Interest Expense and Income*

Interest expense consists primarily of interest expense related to our term loan facility, including amortization of debt discount and issuance costs. Interest income is predominantly derived from investing surplus cash in money market funds and short-term marketable debt securities.

*Other Income (Expense), Net*

Other income (expense), net primarily consists of changes in the fair value of our redeemable convertible preferred stock warrant liability.

**Results of Operations**

**Comparison of the Three Months Ended September 30, 2022 and 2021**

The following table summarizes our results of operations for the periods indicated (in thousands):

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2022 | 2021 | Change | % Change |
| Revenue | $ 11,157 | $ 10,339 | $ 818 | 8 % |
| Cost of goods sold | 3,192 | 2,832 | 360 | 13 % |
| Gross profit | 7,965 | 7,507 | 458 | 6 % |
| **Operating expenses** | | | | |
| Research and development | 5,611 | 4,329 | 1,282 | 30 % |
| Selling, general and administrative | 12,553 | 9,421 | 3,132 | 33 % |
| Total operating expenses | 18,164 | 13,750 | 4,414 | 32 % |
| Loss from operations | (10,199) | (6,243) | (3,956) | 63 % |
| Interest income | 423 | 136 | 287 | 211 % |
| Interest expense | (1,906) | (1,826) | (80) | 4 % |
| Other income (expense), net | (103) | (150) | 47 | (31)% |
| Net loss | $ (11,785) | $ (8,083) | $ (3,702) | 46 % |

***Revenue***

Revenue increased by $0.8 million, or 8%, to $11.2 million during the three months ended September 30, 2022, compared to $10.3 million during the three months ended September 30, 2021. The increase in revenue was primarily due to an increase in the number of products sold for initial implant procedures as well as an increase in pricing in the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. Revenue from sales of our RNS System for replacement procedures represented approximately 17% of our total revenue for the three months ended September 30, 2022 as compared to approximately 24% for the three months ended September 30, 2021. All of our revenue was generated from sales in the United States.

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

Cost of goods sold increased by $0.4 million, or 13%, to $3.2 million during the three months ended September 30, 2022, compared to $2.8 million during the three months ended September 30, 2021. The increase was primarily due to the increase in sales volume, as well as a short-term supply chain disruption that was resolved in the three months ended September 30, 2022. Our gross margin decreased from 72.6% for the three months ended September 30, 2021 to 71.4% for the three months ended September 30, 2022 primarily due to reduced labor absorption resulting from the short-term supply chain disruption.

***Research and Development Expenses***

Research and development expenses increased by $1.3 million, or 30%, to $5.6 million during the three months ended September 30, 2022, compared to $4.3 million during the three months ended September 30, 2021. The increase in research and development expenses was primarily due to an increase of $0.8 million in personnel-related expenses mainly as a result of hiring additional personnel to support product development efforts and clinical studies, an increase of $0.1 million in product development costs, and an increase of $0.3 million in costs associated with our clinical studies.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses increased by $3.1 million, or 33%, to $12.6 million during the three months ended September 30, 2022, compared to $9.4 million during the three months ended September 30, 2021. The increase in selling, general and administrative expenses was primarily due to an increase of $2.7 million in personnel-related expenses mainly as a result of hiring additional sales and marketing personnel and stock-based compensation, and an increase of $0.5 million in sales, field support and marketing costs including contractors and

digital advertising due to an increased focus on marketing activities to support commercial growth and costs associated with preparing to distribute DIXI Medical's product line in the U.S.

***Interest Expense and Income***

Interest expense increased by $0.1 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 due to an increase in average balances of our Term Loan as a result of using the paid-in-kind option for interest whereby we added part of the interest due to the Term Loan's principal balance instead of paying it in cash for the payment dates on June 30, 2022 and September 30, 2022. Interest income increased by $0.3 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021, primarily as a result of higher interest yields in the three months ended September 30, 2022.

***Other Income (Expense), net***

Other income (expense), net increased by less than $0.1 million and was immaterial for both the three months ended September 30, 2022 and 2021.

**Comparison of the Nine Months Ended September 30, 2022 and 2021**

The following table summarizes our results of operations for the periods indicated (in thousands):

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2022 | 2021 | Change | % Change |
| Revenue | $ 32,731 | $ 34,186 | $ (1,455) | (4)% |
| Cost of goods sold | 9,041 | 8,827 | 214 | 2 % |
| Gross profit | 23,690 | 25,359 | (1,669) | (7)% |
| **Operating expenses** | | | | |
| Research and development | 16,857 | 12,866 | 3,991 | 31 % |
| Selling, general and administrative | 37,768 | 27,215 | 10,553 | 39 % |
| Total operating expenses | 54,625 | 40,081 | 14,544 | 36 % |
| Loss from operations | (30,935) | (14,722) | (16,213) | 110 % |
| Interest income | 778 | 262 | 516 | 197 % |
| Interest expense | (5,588) | (5,548) | (40) | 1 % |
| Other income (expense), net | (191) | (5,379) | 5,188 | (96)% |
| Net loss | $ (35,936) | $ (25,387) | $ (10,549) | 42 % |

***Revenue***

Revenue decreased by $1.5 million, or 4%, to $32.7 million during the nine months ended September 30, 2022, compared to $34.2 million during the nine months ended September 30, 2021. The decrease in revenue was primarily due to a decrease in the number of products sold for replacement procedures, partially offset by an increase in revenue from products sold for initial implant procedures in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. Revenue from sales of our RNS System for replacement procedures represented approximately 21% of our total revenue for the nine months ended September 30, 2022 as compared to approximately 26% for the nine months ended September 30, 2021. All of our revenue was generated from sales in the United States.

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

Cost of goods sold increased by $0.2 million, or 2%, to $9.0 million during the nine months ended September 30, 2022, compared to $8.8 million during the nine months ended September 30, 2021. The increase was primarily due to an increase in indirect labor costs including stock-based compensation, partially offset by the decrease in sales volume for replacement procedures in the nine months ended September 30, 2022. Our gross

margin decreased from 74.2% for the nine months ended September 30, 2021 to 72.4% for the nine months ended September 30, 2022 primarily due to higher indirect labor costs.

***Research and Development Expenses***

Research and development expenses increased by $4.0 million, or 31%, to $16.9 million during the nine months ended September 30, 2022, compared to $12.9 million during the nine months ended September 30, 2021. The increase in research and development expenses was primarily due to an increase of $2.7 million in personnel-related expenses primarily due to hiring additional personnel to support product development efforts and clinical studies, an increase of $0.5 million in product development costs, and an increase of $0.8 million in costs associated with our clinical studies.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses increased by $10.6 million, or 39%, to $37.8 million during the nine months ended September 30, 2022, compared to $27.2 million during the nine months ended September 30, 2021. The increase in selling, general and administrative expenses was primarily due to an increase of $5.9 million in personnel-related expenses primarily due to hiring additional personnel and to stock-based compensation, an increase of $2.5 million in general and administrative costs related to operating as a public company, an increase of $1.8 million in sales, field support and marketing costs including travel, contractors, and digital advertising due to an increased focus on marketing activities to support commercial growth and returning operations to pre-pandemic levels, and an increase of $0.3 million in allocated facilities related expenses, including rent, depreciation, information technology costs and utilities.

***Interest Expense and Income***

Interest expense was $5.6 million for the nine months ended September 30, 2022, compared to $5.5 million for the nine months ended September 30, 2021, due to the approximately same average balances of our term loans during the nine months ended September 30, 2022 and 2021. Interest income increased by $0.5 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021, primarily due to an increase in average balances of our money market funds and short-term marketable debt securities and higher interest yields in the nine months ended September 30, 2022.

***Other Income (Expense), net***

Other income (expense), net decreased by $5.2 million to ($0.2) million during the nine months ended September 30, 2022, compared to ($5.4) million during the nine months ended September 30, 2021, primarily due to an increase in the fair value of redeemable convertible preferred stock warrant liability by $5.2 million due to an increase in the fair value of our redeemable convertible preferred stock prior to our IPO in the nine months ended September 30, 2021.

**Liquidity and Capital Resources**

Prior to our IPO, we financed our operations primarily through private placements of equity securities, debt financing arrangements and sales of our RNS System. As of September 30, 2022, we had cash, cash equivalents and short-term marketable debt securities of $85.4 million, compared to $115.6 million at December 31, 2021, and $52.0 million outstanding under the Term Loan, net of debt discount and issuance costs, compared to $49.8 million at December 31, 2021. In September 2020, we entered into the Term Loan for total borrowings of up to $60.0 million and borrowed $50.0 million. In April 2021, we completed our IPO and received $105.5 million in net proceeds after deducting underwriting discounts and commissions and offering costs, of which $4.1 million was used to repay the PPP loan.

***2020 Term Loan***

In September 2020, we entered into the Term Loan with CRG Partners IV L.P. and its affiliates for total borrowings of up to $60 million and borrowed $50 million. The remaining $10.0 million was available to us for borrowing until March 31, 2022 if we achieved a revenue-based milestone in 2021. The revenue-based milestone

was not met, and the remaining $10.0 million of the Term Loan expired without being drawn. The borrowings under the Term Loan are secured by substantially all of our properties, rights and assets, including intellectual property.

The loan bears interest at a rate of 12.5% per year. Payments under the loan are made quarterly with payment dates fixed at the end of each calendar quarter. The loan was interest-only through September 30, 2023, which could be extended through September 30, 2025 at our option if we completed our IPO on or prior September 30, 2023. In connection with closing the IPO, we extended the interest-only period to September 30, 2025. Following the interest-only period, principal payment is due in one installment on September 30, 2025. The Term Loan includes a fee upon repayment of the loan equal to 10% of the aggregate principal amount being prepaid or repaid.

We paid $1.0 million in fees to the lender and third parties which is reflected as a discount on the loan and is being accreted over the life of the loan using the effective interest method.

***Paycheck Protection Program***

In April 2020, we received $4.0 million from a federal Small Business Administration loan under the Paycheck Protection Program. The note bore interest at 1.0% per year on the outstanding principal amount and had a maturity date 24 months from the date of the note. Payments of principal and interest were due from September 2021 through April 2022. In April 2021, we repaid our entire obligation under the PPP Loan amounting to $4.1 million, including principal of $4.0 million and interest of less than $0.1 million, using the proceeds from our IPO.

***Future Funding Requirements***

We expect to incur continued expenditures in the future in support of our commercialization efforts in the United States. In addition, we intend to continue to make investments in clinical studies, development of new products, and other ongoing research and development programs. We may incur additional expenses to expand our commercial organization and efforts, to re-establish operations to pre-pandemic levels, and to plan for continued growth. We may incur additional expenses to further enhance our research and development efforts and to pursue commercial opportunities outside of the United States. We lease our office and manufacturing facilities in Mountain View, California under a non-cancelable operating lease which expires in June 2030. Future minimum lease payments under non-cancelable operating leases were $23.0 million as of September 30, 2022 compared to $6.5 million as of June 30, 2022 due to the amendment to our lease in August 2022 to extend it for an additional six years. See “Facility Lease” in Note 5 to our condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information.

As of September 30, 2022, we had cash, cash equivalents and short-term marketable debt securities of $85.4 million. Based on our current planned operations, we expect that our cash, cash equivalents and short-term marketable debt securities will enable us to fund our operating expenses for at least 12 months from the issuance of our condensed financial statements as of and for the three and nine months ended September 30, 2022. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of medical devices, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the costs of activities related to commercializing and marketing our RNS System in the United States and elsewhere, and manufacturing and distribution costs;
- the research and development activities we intend to undertake, including product enhancements and clinical studies for indication expansions that we intend to pursue;
- the impact of the COVID-19 pandemic on our business;
- the cost of obtaining, maintaining, defending, enforcing, and protecting any patents and other intellectual property rights;

- whether or not we pursue acquisitions or investments in businesses, products or technologies that are complementary to our current business;
- the degree and rate of increased market acceptance of our RNS System in the United States and market acceptance elsewhere;
- our projection related to the DIXI Medical distribution agreement;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence of competing technologies or other adverse market developments.

If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise capital when needed, we will need to delay, limit, reduce or terminate planned commercialization or product development activities in order to reduce costs. In addition, COVID-19 has negatively impacted our business by decreasing and delaying procedures performed to implant our RNS System, and we expect the pandemic will continue to negatively impact our business, which may negatively impact our future liquidity.

***Summary Statements of Cash Flows***

The following table sets forth the primary sources and uses of cash and cash equivalents for the periods presented below (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Net cash provided by (used in): | | |
| Operating activities | $ (29,026) | $ (16,374) |
| Investing activities | 14,899 | (85,242) |
| Financing activities | 628 | 101,615 |
| Net (decrease) in cash and cash equivalents | $ (13,499) | $ (1) |

***Cash Flows Used in Operating Activities***

Net cash used in operating activities was $29.0 million for the nine months ended September 30, 2022. Cash used in operating activities was primarily a result of the net loss of $35.9 million, adjusted for non-cash charges of $11.0 million and change in operating assets and liabilities of $4.1 million. The non-cash charges primarily consisted of $6.3 million of stock-based compensation, $2.0 million of amortization of right-of-use assets, $1.3 million of interest incurred but paid-in-kind and $0.6 million of non-cash interest expense related to our term loan. The change in operating assets and liabilities was due to an increase in accounts receivable of $0.8 million primarily due to slower payments by our customers, an increase in inventories of $1.0 million largely due to an increase in raw materials, a decrease in operating lease liabilities of $2.1 million due to cash paid for rent, and an increase in prepaid expenses and other assets of $0.2 million.

Net cash used in operating activities was $16.4 million for the nine months ended September 30, 2021. Cash used in operating activities was primarily a result of the net loss of $25.4 million, adjusted for non-cash charges of $8.9 million. The non-cash charges primarily consisted of $5.2 million in change in the fair value of redeemable convertible preferred stock warrant liability, $0.6 million of non-cash interest expense related to our term loans, and $2.4 million of stock-based compensation. The change in operating assets and liabilities was due to an increase in prepaid expenses and other assets of $2.2 million primarily due to the timing of payments to our vendors offset in

part by a decrease in accounts receivable of $1.8 million primarily due to more timely payments by our customers, and an increase in accrued liabilities of $1.3 million. The increase in accrued liabilities was primarily the result of the timing of payments to our vendors.

***Cash Flows Provided by (Used in) Investing Activities***

Net cash provided by investing activities was $14.9 million for the nine months ended September 30, 2022, which primarily consisted of sales of marketable debt securities of $15.4 million, which amounts were partially offset by purchases of property and equipment of $0.5 million.

Net cash used in investing activities was $85.2 million for the nine months ended September 30, 2021, which primarily consisted of purchases of marketable debt securities of $85.0 million and purchases of property and equipment of $0.2 million.

***Cash Flows Provided by Financing Activities***

Net cash provided by financing activities was $0.6 million for the nine months ended September 30, 2022, which primarily relates to receipt of proceeds from the issuance of common stock under employee plans.

Net cash provided by financing activities was $101.6 million for the nine months ended September 30, 2021, which primarily relates to receipt of proceeds from our IPO of $109.1 million, partially offset by payment of deferred offering costs of $3.4 million and repayment of debt obligations of $4.1 million under the PPP Loan.

**Critical Accounting Policies and Estimates**

Our financial statements have been prepared in accordance with GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the amounts and disclosures in the financial statements. Our estimates are based on our historical experience, knowledge of current events and actions we may undertake in the future, and on various other factors that we believe are reasonable under the circumstances.

Our critical accounting policies and estimates are described in “Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Estimates” in our Annual Report on Form 10-K filed with the SEC on March 10, 2022. There were no material changes to these accounting policies during the nine months ended September 30, 2022.

**JOBS Act Accounting Election**

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

**Recent Accounting Pronouncements**

See “Recent Accounting Pronouncements” in Note 2 to our unaudited interim condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

***Interest Rate Sensitivity***

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2022, we had cash, cash equivalents and short-term marketable debt securities of $85.4 million, compared to $115.6 million at December 31, 2021, consisting of interest-bearing money market funds and fixed income mutual funds for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents and short-term marketable debt securities, an immediate 10% change in interest rates would not have a material effect on the fair value of our cash equivalents and short-term marketable debt securities.

We do not believe that inflation, interest rate changes or exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

**Item 4. Controls and Procedures**

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as amended) as of September 30, 2022, the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were effective at the reasonable assurance level.

***Remediation of Previously Identified Material Weakness in Internal Control Over Financial Reporting***

We previously disclosed a material weakness in our internal control over financial reporting that existed as of December 31, 2021. We determined that we had a material weakness because we did not design controls to address segregation of duties over the review and approval of account reconciliations and manual journal entries. There were no misstatements as a result of this material weakness; however, it could have resulted in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

With the oversight of senior management and our audit committee, we implemented remediation steps in 2021 including hiring additional accounting personnel and implementing improved accounting and financial reporting procedures and controls. We completed the design, testing and evaluation of new and enhanced internal controls and determined that, as of March 31, 2022, the controls were designed and had operated effectively for a sufficient period of time for our management to conclude that the material weakness had been remediated.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2022 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

We are and from time to time may become subject to legal proceedings. Due to the uncertainty of litigation and depending on the amount and the timing, an unfavorable resolution of some or all of such matters may materially effect our business, results of operations, financial position or cash flows.

For a discussion of our current legal proceedings, please refer to the information set forth under the “Legal Proceedings” section in Note 5, Commitments and Contingencies, in Notes to Condensed Financial Statements in Item 1 of Part I of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

**Item 1A. Risk Factors**

*Investing in our common stock involves a high degree of risk and uncertainty. You should carefully read, consider, and evaluate the risks described below, as well as all of the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Results of Operations," our financial statements and related notes, and our other disclosures and filings. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the market price of our common stock could decline, and you may lose some or all of your investment.*

This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report on Form 10-Q.

**Summary Risk Factors**

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in our common stock speculative or risky include, among others:

- Our sales, business, financial condition and results of operations have been and continue to be impacted by the COVID-19 pandemic;
- We currently rely on our RNS System, which can only be marketed in the United States for use in adults with drug-resistant focal epilepsy, and is recommended as well as implanted primarily at Level 4 CECs. If we are not successful in enhancing awareness of our RNS System, driving adoption across our current target population, expanding beyond Level 4 CECs as well as referral pathways to increase referrals to Level 4 CECs, and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected;
- Our commercial success will continue to depend on attaining significant market acceptance of our RNS System among patients, clinicians and hospital facilities and increasing the number of patients treated at Level 4 CECs and beyond. If we are unable to successfully achieve substantial market acceptance and adoption of our RNS System, our sales, business, financial condition and results of operations will be harmed;
- Our estimates of market opportunity and forecasts of market and revenue growth, including growth in the number of Level 4 CECs, epileptologists and neurosurgeons, as well as our projections related to the DIXI Medical distribution agreement, may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all;
- We depend on a limited number of single-source suppliers and vendors in connection with the manufacture of our products, which makes us vulnerable to supply shortages and price fluctuations that could harm our business, financial condition, and results of operations;
- We may be unable to compete successfully with other treatment options for drug-resistant focal epilepsy, which could harm our sales, business, financial condition and results of operations;
- If adequate reimbursement becomes unavailable for the procedures to implant our RNS System and for clinicians to provide ongoing care for patients treated with our RNS System, it could diminish our sales or affect our ability to sell our RNS System profitably;
- Use of our RNS System requires appropriate neurosurgeon training for implantation and epileptologist training for programming and ongoing patient care, and inadequate training may lead to negative patient outcomes, which could harm our business, financial condition, and results of operations;

- We may not be able to achieve or maintain satisfactory pricing and margins for our RNS System, which could harm our business and results of operations;
- We are seeking expanded FDA labeling for our RNS System to be able to treat patients between the ages of 12 and 17 with drug-resistant focal epilepsy, as well as patients with generalized drug-resistant epilepsy, but if we are unable to broaden the indications for our RNS System to include these patients, our growth potential could be harmed;
- If we fail to comply with U.S. federal and state laws and regulations, including fraud and abuse and other healthcare laws and regulations, such as those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business, financial condition and results of operations could be harmed;
- Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business;
- Our operations are subject to pervasive and continuing FDA regulatory requirements, and failure to comply with these requirements could harm our business, financial condition and results of operations;
- If we are unable to obtain, maintain, protect, enforce and defend patent or other intellectual property protection for our products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, or as a result of our existing or any future out-licenses of our intellectual property, our competitors could develop and commercialize products competitive with ours, and our ability to continue to commercialize our RNS System, or our other products, may be harmed;
- Our collection, use, storage, disclosure, transfer and other processing of sensitive and personal information could give rise to significant costs, liabilities and other risks, including as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices, which may harm our business, financial conditions, results of operations and prospects;
- We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we do achieve profitability, we may not be able to sustain it;
- We previously identified and subsequently remediated a material weakness in our internal control over financial reporting. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations; and
- To support our continued operations and the growth of our business, we may need to seek additional capital through new equity or debt financings, which sources of additional capital may not be available to us on acceptable terms or at all. If we are unable to obtain, if needed, adequate financing or financing on terms satisfactory to us, it could harm our business and growth prospects.

**Risks related to operational, commercial and manufacturing matters**

***Our sales, business, financial condition and results of operations have been and continue to be impacted by the COVID-19 pandemic.***

The global spread of the COVID-19 pandemic, including the different COVID-19 variants and measures introduced by local, state and federal governments to contain the virus and mitigate its public health effects have significantly impacted the global economy and negatively impacted our business. Given the uncertainty around the duration and extent of the COVID-19 pandemic, we expect continued, lingering, and far-reaching adverse impacts to our business, results of operations, financial condition, and liquidity, but cannot accurately predict at this time the extent of the future potential impacts.

Multiple states and local jurisdictions have imposed and continue to maintain government orders and restrictions for their residents to control the spread and ameliorate the impact of COVID-19. Additionally, the Centers for Disease Control and Prevention, or the CDC, and other federal agencies have and may continue to issue additional requirements and guidance relative to actions to be taken by individuals and corporations to reduce the spread of COVID-19. Such orders or restrictions, as well as the perceived need by individuals to continue such practices to avoid infection, among other factors, continue to result in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects. The states in which our RNS System is made, manufactured, distributed, sold, or implanted are and may continue to be in varying stages of addressing the COVID-19 pandemic. We continue to monitor our operations and government mandates. Our primary operations are in Mountain View, California, and as a result of various shelter-in-place and quarantine orders issued by Santa Clara Country and the State of California starting in March 2020, most of our Mountain View-based employees have been telecommuting during the pandemic, which has impacted and may continue to impact certain of our operations over the near and long term. Similar restrictions and orders in other states have limited the ability of our remote sales force to work with physicians and hospitals during the pandemic, which has further impacted and may continue to impact certain of our operations, including our sales process, over the near and long term.

Certain U.S. governmental authorities and certain hospitals have recommended, and in certain cases required, that various elective procedures, including implant procedures for our RNS System, be suspended or canceled to avoid nonessential patient exposure to medical environments and potential infection with COVID-19 and to focus limited healthcare resources and personnel capacity toward the treatment of COVID-19 patients. In addition, hospitals delayed or canceled admissions for epilepsy diagnostic procedures. These actions have resulted in an adverse impact to our ability to sell our RNS System to new and existing customers, customer adoption of our RNS System, and customer use of our RNS System. The disruptions to our activities and operations have negatively impacted and may continue to negatively impact our business, operating results and financial condition. Our sales were particularly negatively impacted in the third and fourth quarters of 2021 as well as the first half of 2022, as a result of Delta and Omicron variant headwinds and we expect the COVID-19 related adverse impact to continue into 2022. Specifically, in the third quarter of 2021 and in part as a result of the COVID Delta variant, our business was negatively impacted by decreased and delayed procedures being performed to implant our RNS System, delayed and decreased epilepsy diagnostic evaluations at epilepsy monitoring units, or EMUs, as well as increased vacation demand as a result of loosening travel restrictions and hospital staffing shortages, which we believe may continue throughout the pandemic. We saw additional impact in the fourth quarter of 2021 and the first half of 2022 as a result of continued Delta variant headwinds and new headwinds from the Omicron variant. We expect to see continued impact from the Omicron variant as well as other variants in 2022. We may also continue to see an impact on the sales of our RNS System as a result of hospital staffing shortages as well as seasonality, which, as COVID variants continue to emerge and certain pandemic restrictions are tightened then relaxed and physicians and patients take vacations, may result in additional reduction in both preimplantation diagnostic procedures as well as RNS implant and replacement procedures.

The widespread pandemic has also had a significant negative effect on the U.S. and global economies and, if the COVID-19 pandemic results in a prolonged economic recession, it would continue to harm our sales, business, operating results, and financial condition.

The impact of COVID-19 on our sales and operations has resulted in changes to the way our resources are allocated, including reduced resources to conduct further clinical studies. Additionally, restrictions on the ability to travel, social distancing policies, orders and restrictions, including those described above, and fears of COVID-19 spreading within hospital facilities, continue to limit access to hospitals or other clinical study sites and create challenges for enrolling and monitoring patients in clinical studies, which has and may further impact our current and future clinical study plans.

Quarantines or government reaction or shutdowns for COVID-19 have disrupted and may disrupt our supply chain, especially for components we source from single-source suppliers. Travel and cargo restrictions may also disrupt our ability to distribute our RNS System or engage with our customers in the ordinary course of business. Any cargo restrictions related to raw materials used to manufacture our RNS System or its components may restrict our ability to manufacture and ship devices and harm our sales, business, operating results, and financial condition.

Our key personnel and other employees have and could continue to be affected by COVID-19. Illness, or the fear of illness, in our workforce as a result of COVID-19, have resulted and may result in reduced availability and productivity. In addition, we have taken and may take additional cost saving measures that lead to reductions in force, furloughs, or altered job responsibilities. These measures could reduce the efficiency of our operations or prove insufficient. Additionally, we have delayed and reduced, and may continue to delay or reduce, certain critical research, development, capital spending, and other projects as a result of COVID-19, which will delay the completion of such projects.

We rely on strong working relationships with epileptologists, neurosurgeons and other medical professionals, as well as the support of key opinion leaders, to market our RNS System. Our sales and marketing personnel rely significantly on in-person and onsite access to clinicians and hospital facilities, primarily Level 4 CECs and programming centers, which has been and continues to be restricted as hospital facilities respond to new COVID variants, including the Delta and Omicron variants, by reducing access to essential personnel and patients. The COVID-19 pandemic has restrained, and will likely continue to restrain, access to clinicians and hospital facilities by our sales and marketing team, which will harm our ability to contract with new Level 4 CECs or programming centers, expand our reach within Level 4 CECs and programming centers, and drive referrals to Level 4 CECs. These restrictions have harmed our sales and marketing efforts, and continued restrictions would have a negative impact on adoption of our RNS System and, as a result, a negative impact on our sales, results of operations and financial condition.

Limited supplies of vaccines, including booster shots, personal protective equipment and COVID-19 testing supplies may further reduce onsite access for our personnel and may delay the lifting of restrictions on elective procedures, including implant procedures for our RNS System.

***We currently rely on our RNS System, which can only be marketed in the United States for use in adults with drug-resistant focal epilepsy, and is recommended as well as implanted primarily at Level 4 CECs. If we are not successful in enhancing awareness of our RNS System, driving adoption across our current target population, expanding beyond Level 4 CECs as well as referral pathways to increase referrals to Level 4 CECs, and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected.***

Our business currently depends primarily on our ability to successfully market our RNS System, which includes increasing the number of patients treated at CECs, increasing adoption of our RNS System across CECs, and driving utilization by clinicians within CECs. Currently, our RNS System can only be marketed for use in adults with drug-resistant focal epilepsy in the United States. Additionally, our RNS System is primarily recommended and implanted at Level 4 CECs, which provide advanced diagnosis and management of epilepsy. Therefore, we are dependent on widespread market adoption of our RNS System within a limited number of accounts. We are aiming to expand the population of patients we can treat with our RNS System, as well as the number of physicians that can prescribe and the number of centers at which neurosurgeons can implant our RNS System, but there can be no assurance that we will succeed.

The commercial success of our RNS System will continue to depend on a number of factors, including the following:

- the degree to which drug-resistant epilepsy remains a chronic and debilitating condition;
- the actual and perceived effectiveness, safety and reliability, and clinical benefit, of our RNS System, especially relative to alternative neuromodulation devices such as VNS or DBS;
- the prevalence and severity of any adverse patient events involving our RNS System;
- the degree to which clinicians, patients and hospital facilities, primarily Level 4 CECs, adopt our RNS System;
- the continued effects of the COVID-19 pandemic;

- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for epilepsy;
- the results of additional clinical and other studies relating to the health, safety, economic or other benefits of our RNS System;
- whether key thought leaders in the medical community accept that our clinical efficacy and safety results are sufficiently meaningful to influence their decision to adopt our RNS System over other neuromodulation therapies;
- the extent to which we are successful in educating clinicians, patients, and hospital facilities about the benefits of our RNS System, including as a result of the extended battery life of the neurostimulator;
- our reputation among clinicians, patients and hospital facilities;
- our ability to predict product performance;
- the strength of our marketing and distribution infrastructure, including our ability to drive adoption and utilization of our RNS System at Level 4 CECs and beyond, our ability to develop and maintain relationships with programming centers, and our ability to expand referral pathways to CECs;
- our ability to obtain, maintain, protect, enforce and defend our intellectual property rights, including in and to our RNS System;
- our ability to maintain compliance with all legal and regulatory requirements, including those applicable to our RNS System;
- our ability to continue to maintain a commercially viable manufacturing process at our manufacturing facility that is compliant with current Good Manufacturing Practices, or cGMP, and Quality Systems Regulations, or QSR;
- our ability to maintain our contractual relationships with our vendors and component suppliers, including single-source vendors and suppliers, through which we obtain critical components for our RNS System;
- the continued coverage of and adequate payment for the implantation procedure and for clinicians to provide ongoing care for patients implanted with our RNS System by third party payors, including both private and government payors; and
- our ability to continue to attract and retain key talent.

If we fail to successfully market and sell our RNS System cost-effectively and maintain and expand our market share, our sales, business, financial condition and results of operations will be negatively affected.

***Our commercial success will continue to depend on attaining significant market acceptance of our RNS System among patients, clinicians and hospital facilities and increasing the number of patients treated at Level 4 CECs and beyond. If we are unable to successfully achieve substantial market acceptance and adoption of our RNS System, our sales, business, financial condition and results of operations would be harmed.***

Our commercial success will depend in large part on the further acceptance by clinicians, patients and hospital facilities of our RNS System as safe, useful, and cost-effective, and increasing the number of patients treated at Level 4 CECs. We cannot predict how quickly, if at all, additional clinicians, patients, and hospital facilities will adopt our RNS System over continued noninterventional therapies or competing neuromodulation devices or surgical treatment options at Level 4 CECs and beyond. For example, clinicians may be reluctant to use our RNS System due to familiarity with neuromodulation devices that are more established. Clinicians, patients, and hospital facilities may continue to prefer noninvasive therapeutic options, resective or ablative surgery, or alternative neuromodulation therapies such as VNS and DBS. Moreover, we cannot predict how quickly, if at all, those currently suffering from epilepsy but who are not being treated will seek treatment or utilize Level 4 CECs for

treatment. Our ability to grow sales of our RNS System and drive market acceptance will depend on successfully educating clinicians, patients, and hospital facilities of the relative benefits of our RNS System.

Additionally, patients rely on their healthcare providers, including epileptologists and neurosurgeons to recommend a course of treatment. If we are unable to successfully achieve substantial market acceptance and adoption of our RNS System by additional clinicians, patients, and hospital facilities, patients may be reluctant to use our products over alternative neuromodulation therapies. If we are unable to successfully drive patient interest in our RNS System, our business, financial condition and results of operations would be harmed.

***Our commercial success will depend on a continued flow of patient referrals to Level 4 CECs from treating primary care physicians, neurologists, and other healthcare providers and from caregiver support and encouragement around physician referrals and self-referrals to Level 4 CECs. If we are unable to successfully expand our referral pathways to achieve an increased patient referral pipeline into Level 4 CECs, our sales, business, financial condition and results of operations would be harmed.***

Our commercial success will depend in large part on continued referrals of appropriate patients from treating primary care physicians, neurologists, and other healthcare providers to epileptologists, neurosurgeons, and other clinicians, primarily at Level 4 CECs. We estimate that of the approximately 575,000 adults with drug-resistant focal epilepsy in the United States, approximately 24,000 adult drug-resistant focal epilepsy patients are treated in Level 4 CECs annually. We cannot predict how quickly, if at all, we can build that pipeline through our sales and marketing efforts and whether primary care physicians, neurologists, and other healthcare providers, as well as caregivers will support patient referrals to epileptologists and neurosurgeons at Level 4 CECs over other therapy options.

Primary care physicians, neurologists, and other healthcare providers may continue to prefer traditional treatments, such as additional attempts to treat with new therapeutic drugs that become available from time to time, including for fear of losing management of the patient's care. If we are unable to educate clinicians to follow national guidelines, which recommend that patients whose seizures have not been brought under control after three months of care by a primary care physician or after 12 months of seeing a general neurologist be referred to a CEC, we may be unable to successfully build our patient pipeline. This could harm our business, financial condition and results of operations.

***Various factors outside our direct control, including the COVID-19 pandemic, may negatively impact our manufacturing of our RNS System, which could harm our business, financial condition, and results of operations.***

We manufacture our RNS System at our manufacturing facility in Mountain View, California. This facility supports our production operations, including manufacturing, quality control, and raw material and finished goods storage. We believe that we currently have adequate manufacturing capacity and supplies for our products sufficient to meet our demand forecasts. If demand for our RNS System increases more rapidly than we anticipate, if we encounter problems with one or more of our suppliers, or if we secure regulatory approval to commercialize our products in additional geographies or indications, we may need to either expand our manufacturing capabilities, qualify new suppliers, or outsource to other manufacturers.

Our manufacturing and distribution operations are subject to regulatory requirements of the FDA's Quality System Regulation, or QSR, for medical devices sold in the United States. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements, and foreign regulations, to the extent applicable. If we fail to manufacture our products in compliance with QSR, or if our manufacturing facility suffers disruptions, supply chain issues, machine failures, slowdowns or disrepair, we may not be able to fulfill customer demand and our business would be harmed. Further, we typically do not maintain more than several months of inventory on hand and we manufacture our products using near term demand forecasts. As a result, deviations from our forecasts could cause us to fail to meet demand for our products.

Since we produce our products in one manufacturing facility, any contamination of the controlled environment, equipment malfunction, supply issues, personnel issues, including human error, or failure to strictly follow procedures can significantly reduce our yield. A drop in yield can increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources. In addition, if demand for our products shifts such that our manufacturing facility is operated below our forecasts for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

The manufacturing, sterilization and distribution of our products are technically challenging. Changes that our suppliers may make, or additional requirements from regulatory agencies, outside of our direct control can have an impact on our processes, on quality and on the successful or timely delivery of our products to our customers. Mistakes and mishandling may occur, which can affect supply and delivery. As a result, our dependence on third-party, including single source, suppliers, subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, financial condition, and results of operations, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations, including due to the COVID-19 pandemic;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to produce components that consistently meet our quality specifications;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of our products;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and other Federal and state regulatory authorities;
- delays in regulatory approvals of any changes to manufacturing, including the use of new suppliers;
- latent defects that may become apparent after our products have been released and that may result in an adverse event or a recall of such products;
- inclusion of vendors of raw materials not in compliance with regulatory requirements;
- natural or other disasters, global pandemics, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment, international conflict or war, or other forms of disruption to business operations affecting our manufacturer or its suppliers;
- production delays related to the evaluation and testing of our products or the use of components from alternative suppliers;
- failure to complete sterilization on time or in compliance with the required regulatory standards; and
- delays in delivery by our suppliers of components, materials, or services due to changes in demand from us or their other customers.

The occurrence of any of these issues could significantly harm our ability to manufacture our products and maintain sufficient quality standards, which would negatively impact our sales, business, financial condition, and results of operations.

***We depend on a limited number of single-source suppliers and vendors in connection with the manufacture of our RNS System, which makes us vulnerable to supply shortages and price fluctuations that could harm our business, financial condition, and results of operations.***

We source and rely upon materials, components, and sub-assemblies of our RNS System, as well as manufacturing services from approved suppliers, most of which are single source suppliers. For example, Micro Systems Technologies Management AG and Greatbatch Ltd are single source suppliers of several key components of our products, including printed circuit assemblies and batteries. In addition, certain of our suppliers are not under long-term contracts with us.

These components, materials, and services, which also include silicone adhesive, integrated circuits, and other components, are critical and there are relatively few alternative sources of supply. We believe our single source suppliers are capable of continuing to meet our specifications and maintaining quality, but any significant problem experienced by one of our single source suppliers may result in a delay or interruption in the supply of components, materials, or services to us. Our suppliers may experience manufacturing delays or issues, stop producing our components, materials, or services, increase the prices they charge us, or elect to terminate their relationships with us. In any of these cases, we could face a delay of several months to identify, perform appropriate testing, and qualify alternative suppliers and service providers with regulatory authorities, as we do not currently have supplier transition plans. In addition, the failure of our third-party suppliers and service providers to maintain acceptable quality requirements could result in the recall of our products. If one of our suppliers fails to maintain acceptable quality requirements, we may have to identify and qualify a new supplier. Although we require our third-party suppliers to supply us with materials, components and services that meet our specifications and comply with applicable provisions of the FDA's QSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the materials and components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner.

The number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited and certification of a new supplier may be complex and time consuming. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate regulatory authorities, including the FDA. The added time and cost to arrange for alternative suppliers could harm our business. New manufacturers of any planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the planned product. Obtaining the necessary FDA or international approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property or other proprietary rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

***If we fail to optimize our sales and marketing capabilities and develop widespread brand awareness cost-effectively, our growth will be impeded and our business may suffer.***

We are actively expanding our presence in the United States through additional sales and education efforts to drive awareness of our RNS System amongst patients, clinicians and hospital facilities, to drive adoption of our RNS System at Level 4 CECs and increase utilization of our RNS System within new and existing accounts. We also plan to explore regulatory and reimbursement approval pathways to expand our presence in international territories.

We take a measured approach to optimize our sales infrastructure to grow our customer base and our business. Identifying and recruiting qualified personnel and training them on the use of our RNS System, on applicable federal and state laws and regulations and on our internal policies and procedures, requires significant time, expense and attention, particularly given our strategy of having each Therapy Consultant, or sales representative, cover many accounts. It can take significant time before our Therapy Consultants are fully trained and productive and before they have established relationships with their target accounts. Our business may be harmed if our efforts to optimize do not generate a corresponding increase in revenue or result in a decrease in our operating margin. In particular, if

we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue.

We dedicate significant financial and other resources to our customer outreach and training programs, which may require us to incur significant upfront costs. For example, we may need to conduct additional physician trainings across hospital facilities, including Level 4 CECs. Our sales force may also need to develop additional efficiencies and approaches to address potential growth as we expand referral pathways, expand into additional existing Level 4 CECs as well as new Level 4 CECs, and increase the number of epileptologists recommending, and neurosurgeons implanting, our RNS System within each Level 4 CEC. Our business would be harmed if our programs and associated expenditures do not generate a corresponding increase in revenue.

In addition, we believe that developing and maintaining awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenue and, even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to realize a sufficient return on our brand-building efforts, or to achieve the widespread brand awareness that is critical for broad adoption of our RNS System.

***We may be unable to compete successfully with other treatment options for drug-resistant focal epilepsy, which could harm our sales, business, financial condition and results of operations.***

Our industry is competitive and has been evolving rapidly with not only existing treatment options, but also the introduction of new products and technologies as well as the market activities of industry participants. Our RNS System is indicated for adult patients with drug-resistant focal epilepsy in the United States and we primarily market our device to customers, primarily consisting of the clinicians within Level 4 CECs that treat these patients. In our target patient population, there are two primary treatment options (i) an ablative or resective surgery, or (ii) implantation of a neuromodulation device. Patients may also choose not to actively seek additional treatment for epilepsy or may choose to try new therapeutic drugs that become available from time to time. We estimate that approximately 80% of drug-resistant focal epilepsy patients are either not ideal candidates for ablative or resective surgery or are unwilling to undergo a destructive surgical procedure and we compete primarily with two manufacturers of neuromodulation devices for the treatment of these patients. Our primary competitors are LivaNova plc, which manufactures the VNS System, and Medtronic plc, which manufactures the DBS System. Third-party payors may encourage the use of competitors' products or other neuromodulation therapies due to lower costs of competing products or alternatives. Additionally, treating physicians, including epileptologists and neurosurgeons may promote the use of other competitors' products or alternative therapies. Further, as existing competitors and other companies develop new or improved products, we cannot predict what the standard of care will be in the future.

Our primary competitors are large, well-capitalized companies with significant market share and resources. They have more established sales and marketing programs than we do and have greater name recognition. These competitors also have long operating histories and may have more established relationships with potential customers. In addition to competing for market share, competitors may develop or acquire patents or other rights that may limit our ability to compete.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. There can be no assurance that other companies or institutions will not succeed in developing or marketing devices and products that are more effective or safer than our RNS System or that would render our RNS System obsolete or noncompetitive.

We believe that the clinical advantages of our RNS System and our focus on neuromodulation will be important factors in our future success. Our continued success depends on, among other things, our ability to:

- continue to demonstrate safety and efficacy in our Post-Approval Study and in ongoing commercial use;
- expand our referral pathways;

- expand the number of Level 4 CECs implanting our RNS System and increase utilization across these Level 4 CECs;
- drive awareness to increase the number of drug-resistant epilepsy patients referred to Level 4 CECs;
- maintain adequate reimbursement for implant procedures and for clinicians to provide ongoing care of patients treated with our RNS System;
- attract and retain skilled research, development, sales, marketing and clinical personnel;
- continue to innovate in order to improve therapy effectiveness and enhance the patient and provider experience;
- adequately predict product performance;
- obtain and maintain regulatory clearances and approvals, including for expanded indications;
- cost-effectively manufacture, market and sell our RNS System;
- obtain, maintain, protect, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others;
- acquire products or technologies complementary to or necessary for our business; and
- source materials, components, and sub-assemblies from suppliers on a cost-effective and timely basis.

***Adoption of our RNS System depends on positive clinical data as well as clinician acceptance of the data and our products, and negative clinical data or perceptions among these clinicians would harm our sales, business, financial condition, and results of operations.***

The rate of adoption and sales of our products are heavily influenced by clinical data. Although we have positive clinical data across four multi-center FDA approved prospective clinical studies going out as far as nine years, there can be no assurance that clinical data will continue to be positive for our ongoing studies, such as our Post-Approval Study. Additionally, there can be no assurance that future clinical studies, including those to continue demonstrating the efficacy of our products in currently approved patient populations and those to support label retention and expansion for our products will demonstrate safety and effectiveness. Unfavorable or inconsistent clinical data from ongoing or future clinical studies conducted by us, our competitors, or third parties, the negative interpretation of our clinical data internally and externally, including by customers, competitors, patients, and regulators, or findings of new or more frequent adverse events, could harm our business, financial condition, and results of operations.

The rate of adoption and sales of our products are also influenced by clinician perceptions. Negative perceptions of our products by clinicians, including due to negative clinical data, could result in decreased adoption or use of our products, which would harm our business, financial condition, and results of operations. Additionally, if key opinion leaders who support our products cease to recommend our products, our business, financial condition and results of operations will be harmed. Further, if we cannot maintain strong working relationships with clinicians and continue to receive their advice and input, the marketing of our products could suffer, which could harm our business, financial condition and results of operations. The COVID-19 pandemic and related restrictions on access to clinicians as well as hospital staffing shortages have impacted, and will likely continue to impact, our ability to maintain such relationships. Finally, although we have demonstrated the safety, effectiveness and clinical advantages of our products in pivotal clinical studies, neuromodulation is still a relatively new approach to treating drug-resistant focal epilepsy. The results of clinical studies of the products conducted to date and from commercial use do not necessarily predict future results. Any negative long-term results or adverse events from use of our products that arise in the future could harm our business, financial condition, and results of operations.

Our future success also depends upon patients having an understanding of how to properly use our RNS System and an experience with our products that meets their expectations in order to increase clinician demand for our

products as a result of positive feedback and word-of-mouth. Patients may be dissatisfied if their expectations of the procedure and results are not met or if they are not adequately trained on use of our RNS System. Patients may be dissatisfied if they experience adverse events or insufficient reduction in frequency of seizures. If the results of our products do not meet the expectations of the patients, or the patient experiences adverse events, it could discourage the patient from continuing to use our device or referring our products to others. Dissatisfied patients may express negative opinions through social media, advocacy, or other publicity. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales.

***If adequate reimbursement becomes unavailable for the procedures to implant our RNS System and for clinicians to provide ongoing care for patients treated with our RNS System, it could diminish our sales or affect our ability to sell our RNS System profitably.***

The implant procedure for our RNS System and the ongoing patient care provided by clinicians, including monitoring and programming, are reimbursed under well-established physician and hospital codes. Our ability to increase sales of our RNS System depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations, and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. We do not bill any third-party payors for our RNS System. Instead, we invoice healthcare providers for our RNS System and the cost is bundled into the reimbursement received by healthcare providers for the procedures in which our RNS System is used.

We expect our RNS System will continue to be purchased by hospital facilities, primarily Level 4 CECs, and other providers who will then seek reimbursement from third-party payors for brain-responsive neuromodulation for drug resistant focal epilepsy. While third-party payors currently cover and provide reimbursement for both implant procedures of our RNS System as well as for clinicians providing ongoing patient care, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement, or that current reimbursement levels for implant procedures as well as clinician-provided ongoing patient care will continue.

Furthermore, the overall amount of reimbursement available for brain-responsive neuromodulation for drug resistant focal epilepsy could decrease in the future. Changes in reimbursement may not necessarily impact our sales. Additionally, we cannot be sure that the reimbursement amounts available for brain-responsive neuromodulation for drug resistant focal epilepsy will not reduce or otherwise negatively impact the demand for our marketed RNS System. Failure by Level 4 CECs and other users of our RNS System to obtain coverage and adequate reimbursement for the implant procedures or for clinicians providing ongoing patient care would cause our business, financial condition, and results of operations to suffer.

***Use of our RNS System requires appropriate neurosurgeon training for implantation and epileptologist training for programming and ongoing patient care, and inadequate training may lead to negative patient outcomes, which could harm our business, financial condition, and results of operations.***

The successful use of our RNS System depends in part on the training and skill of the neurosurgeon performing the implant procedure as well as the clinician, typically an epilepsy specialist, performing the subsequent programming of our RNS System and monitoring the patient response. Clinicians could experience difficulty with the technique necessary to successfully implant and program our RNS System, and monitor patients if they do not receive appropriate training. Moreover, clinicians rely on their previous medical training and experience when recommending or implanting our RNS System, and we cannot guarantee that all neurosurgeons will have the necessary implantation skills to properly perform the procedure. We cannot be certain that physicians or healthcare providers that use our RNS System have received sufficient training, and physicians or healthcare providers who have not received adequate training may nonetheless attempt to use our RNS System with their patients. If clinicians implant or utilize our RNS System incorrectly, or without adhering to or completing all relevant training, their patient outcomes may not be consistent with the outcomes achieved in our clinical studies. Adverse safety outcomes that arise from improper or incorrect use of our RNS System may negatively impact the perception of patient benefit and safety of our RNS System, notwithstanding results from our clinical studies. These results could limit adoption

of our RNS System in treatment for drug-resistant focal epilepsy, which would harm our sales, business, financial condition, and results of operations.

***We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.***

We are highly dependent on our senior management and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, engineers, scientists, clinical trial specialists and other highly skilled personnel and to integrate current and additional personnel in all departments. As part of our expense management initiatives, we recently implemented a pause on hiring for certain open positions and implemented other reductions across the entire organization, including workforce reductions. The pause on hiring, or turnover or reductions of members of our senior management, sales and marketing professionals, engineers, scientists and clinical trial specialists could impact decision-making and could result in delays in product development and harm our business.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and other key personnel may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

We rely on our own direct sales force to market and sell our RNS System, and if we are unable to optimize our sales force, it could harm our business. Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team. If our employees fail to adequately promote, market and sell our products, our sales could significantly decrease. As we launch new products, expand our product offerings and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled employees with significant technical knowledge in various areas. An inability to attract, hire, train and retain employees will harm our sales, business, financial condition, and results of operations.

***We expect to increase the size of our organization in the future, and we may experience difficulties in managing the operational elements or timing of this growth. If we are unable to manage or appropriately time the anticipated growth of our business, our future revenue and operating results may be harmed.***

As of September 30, 2022, we had 174 employees. As our sales and marketing strategies develop and as we continue our transition of operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully market and sell our RNS System will depend, in part, on our ability to effectively manage or time any future growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

As demand for our RNS System increases, we will need to continue to scale our capacity at our manufacturing facility, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot be certain that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation will be harmed and our business will suffer. Additionally, additional growth may result in higher fixed costs and may slow our ability to reduce costs in the face of a sudden decline in demand for our products.

***We may not be able to achieve or maintain satisfactory pricing and margins for our RNS System, which could harm our business and results of operations.***

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to maintain satisfactory prices for our RNS System at the levels we have historically achieved. The pricing of our products could be impacted by several factors, including pressure to reduce prices by our customers due to a decline in the amount that third-party payors reimburse for implant procedures using our RNS System for clinicians providing ongoing patient care. A decline in the amount that third-party payors reimburse our customers for ongoing patient care could also make it difficult for programming centers to conduct ongoing patient support without a corresponding reduction in prices for our products. If we are forced to lower or are unable to increase the price we charge for our RNS System, our gross margins will decrease, which will harm our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode, which could harm our business and results of operations.

***Our results of operations may be harmed if we are unable to accurately forecast customer demand for our products.***

We do not maintain large amounts of excess inventory at any given time. To ensure adequate supply, we must forecast inventory needs and manufacture our products based on our estimates of future demand. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, our inability to forecast the lifecycle of our products, an increase or decrease in customer demand for our products or for competitor products, our failure to accurately forecast customer adoption of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions, as well as the ongoing COVID-19 pandemic. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our products, our manufacturing team may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of components, materials, or services, or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, which may negatively affect our business, financial condition, and results of operations.

***We are seeking expanded FDA labeling for our RNS System to be able to treat patients between the age of 12 and 17 with drug-resistant focal epilepsy, as well as patients with generalized drug-resistant epilepsy, but if we are unable to broaden the indications for our RNS System to include these patients, our growth potential could be harmed.***

Our products are subject to extensive regulation by the FDA in the United States. Before a new medical device or a new intended use for an existing medical device can be marketed in the United States, we must first submit and receive either 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, or the FDCA, or approval of a PMA application from the FDA, unless an exemption applies.

If clinical studies do not produce results necessary to support regulatory clearance or approval to expand our indications to include patients age 12 to 17 with drug-resistant focal epilepsy or patients with generalized drug-resistant epilepsy, we will be unable to obtain and maintain necessary approvals to expand our indications to include

these patients in accordance with our expected timelines, which could harm our growth potential. Furthermore, we could incur substantial costs and the attention of management could be diverted throughout this process.

***We may expand sales of our RNS System internationally in the future, but we may experience difficulties in obtaining regulatory clearance or approval or in successfully marketing our RNS System internationally even if approved. A variety of risks associated with marketing our RNS System internationally could harm our growth potential.***

While our RNS System is not yet approved for sale outside the United States, we may pursue regulatory and reimbursement approval pathways in markets outside of the United States. Sales of our RNS System outside of the United States will be subject to foreign regulatory requirements governing clinical studies and marketing approval, as well as additional post-approval requirements. We would incur substantial expenses in connection with any international expansion. Additional risks related to operating in foreign countries include:

- differing regulatory requirements in foreign countries, including with respect to data privacy and security;
- differing reimbursement regimes in foreign countries, including price controls;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenue;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights as well as intellectual property theft or compulsory licensing, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and
- business interruptions resulting from geopolitical actions, including tariffs, war and terrorism.

These and other risks associated with international operations may harm our ability to attain or maintain profitable operations internationally, which would harm our growth potential.

In addition, there can be no guarantee that we will receive approval to sell our RNS System in every international market we target, nor can there be any guarantee that any sales would result even if such approval is received. Approval in the United States, or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties and costs for us and require additional studies and additional expenses. Regulatory requirements can vary widely from country to country and could delay the introduction of our RNS System in those countries. If we fail to comply with these regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue will be diminished. Our inability to successfully enter all our desired international markets and manage business on a global scale could harm our growth potential.

Further, there are foreign privacy laws and regulations that impose restrictions on the collection, use, storage, disclosure, transfer and other processing of personal data, including health information. For example, the European Union General Data Protection Regulation, or the GDPR, imposes stringent data protection requirements, including,

for example, more robust disclosures to individuals, a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations regarding third-party processors in connection with the processing of the personal data. Our failure to comply with the GDPR or other applicable foreign privacy laws or regulations or significant changes in the laws and regulations restricting our ability to obtain or use required patient information could significantly impact our business and our future business plans.

**Risks related to government regulation and our industry**

***If we fail to comply with U.S. federal and state laws and regulations, including fraud and abuse and other healthcare laws and regulations, such as those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business, financial condition and results of operations could be harmed.***

Healthcare providers play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have or obtain marketing clearance or approval. Through our arrangements with healthcare professionals and hospital facilities, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees, contractors, and other third parties, including our customers, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal civil False Claims Act, or the FCA. Our relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws. There are also similar laws in other countries that we may become subject to if we expand internationally.

The laws that may affect our ability to operate include, among others:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws, including the FCA, and civil monetary penalties laws, which prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government;
- the Health Insurance Portability & Accountability Act of 1996, or HIPAA, which applies to our customers and some of their downstream vendors and contractors, imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- various state laws governing the privacy and security of personal information, including the California Consumer Privacy Act, or the CCPA, which became effective on January 1, 2020, and California Privacy Rights Act of 2020, or the CPRA, which amends and expands the CCPA and goes into effect in January 2023, which regulates the processing of personal information of California residents and increases the

privacy and security obligations of covered companies handling such personal information. The CCPA and the CRPA requires covered companies to, amongst other things, provide new and additional disclosures to California residents, and affords such residents new abilities to access their personal information and opt out of certain sales of personal information; and

- the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians, as defined by such law, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018, or the BBA, increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient care programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil FCA and HIPAA's healthcare fraud and privacy provisions.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling federal civil FCA, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the Office of Inspector General, or OIG, in order to avoid exclusion from participation (such as loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs and operational burdens on companies to ensure compliance. Defending against any such actions can be detrimental to our reputation and brand and can otherwise be costly, time-consuming and may require significant personnel resources, and may harm our business, financial condition and results of operations.

In addition, the medical device industry's relationship with physicians is under increasing scrutiny by the OIG, the U.S. Department of Justice, or the DOJ, the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorney generals and other government agencies, could harm our business, financial condition and results of operations.

***Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business, financial condition and results of operations.***

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate

reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical studies.

We have adopted a code of conduct, employee handbook, and compliance policies, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in integrity issues, or a negative impact to our reputation or brand. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations.

***Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.***

The FDA and similar agencies regulate our products as medical devices. Complying with these regulations is costly, time-consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for an existing device, can be marketed in the United States, a company must first submit and receive either 510(k) clearance or approval of a PMA from the FDA, unless an exemption applies. FDA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- product design, development, manufacturing (including suppliers) and testing;
- laboratory, preclinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Our products are subject to extensive regulation by the FDA and if we expand internationally in the future may be subject to extensive regulation by non-U.S. regulatory agencies. Further, improvements of our existing products, any potential new products, and new indications for use of our current products will be subject to extensive regulation, and we may require permission from regulatory agencies and ethics boards to conduct clinical studies, as well as clearance or approval from the FDA prior to commercial sale. In order to commercialize and distribute our products in markets outside of the United States, it will require approval from non-U.S. regulatory agencies.

The FDA and foreign regulatory bodies can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical studies or the interpretation of data from clinical studies;
- serious and unexpected adverse device effects experienced by participants in our clinical studies;
- the data from our preclinical studies and clinical studies may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing or labeling our RNS System, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, and total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could harm our business, financial condition and results of operations.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- removal from FDA's Voluntary Improvement Program pilot;
- unanticipated expenditures to address or defend such actions;
- form 483s, or other compliance or enforcement notices, communications or correspondence, including customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our RNS System;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA of new products or modified products;
- operating restrictions;
- seizure or detention of products;
- withdrawing 510(k) clearances or PMAs that have already been granted;

- refusal to grant export approval for our RNS System;
- criminal prosecution; or
- civil penalties.

If any of these events were to occur, it would have a negative impact on our business, financial condition and results of operations.

The FDA also regulates the advertising and promotion of our RNS System to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Additionally, our manufacturing facility is required to comply with extensive requirements imposed by the FDA, including ensuring that quality control and manufacturing procedures conform to the QSR. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510(k) or PMA application.

The 510(k) or PMA process can be expensive, lengthy and unpredictable and we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We may not be able to obtain necessary clearances or approvals or may be unduly delayed in doing so, which would negatively affect our business, financial condition and results of operations. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained PMA approval to market our RNS System, our approval can be revoked if safety or efficacy problems develop.

***Our operations are subject to pervasive and continuing FDA regulatory requirements, and failure to comply with these requirements could harm our business, financial condition and results of operations.***

Before a new medical device or service, or a new intended use for an existing product or service, can be marketed in the United States, a company must first submit and receive either 510(k) clearance or PMA from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is substantially equivalent to a legally-marketed predicate device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device.

In the process of obtaining PMA approval, which was required for our RNS System, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical study, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable device.

The FDA and state and international authorities have broad enforcement powers. The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices and product quality management. Such reviews and investigations may result in: civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies; and result in our incurring substantial unanticipated costs and the diversion of key personnel and management’s attention from their regular duties, any of which may harm our business, financial condition and results of operations, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of interactions with healthcare providers. For example, Open Payments requires us to annually report to CMS payments and other transfers of value to U.S. physicians and certain other clinicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which could harm our business, financial condition and results of operations.

***Modifications to our products may require new 510(k) clearances or PMAs or may require us to recall or cease marketing our products until clearances or approvals are obtained, which could harm our business, financial condition and results of operations.***

In the United States, our RNS System is marketed pursuant to a PMA order issued by the FDA. Any modifications to a PMA-approved device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires approval of a new PMA application or PMA supplement. For instance, we believe that the change in the expected average battery life of our RNS System requires a label change, and we have submitted this to the FDA as a PMA supplement for review. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30-Day Notice, Special PMA Supplement - Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new approvals are necessary. If the FDA disagrees with our determination and requires us to seek new PMA approvals for modifications to our previously approved products for which we have concluded that new approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

For products that have received 510(k) clearance, such as our Burr Hole Cover product, modifications that could significantly affect safety and effectiveness, such as changes to the intended use or technological characteristics, may require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance, or if such modification put the device into Class III, possibly a PMA. We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

We have made modifications to our RNS System in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified, which could harm our operating results and require us to redesign such products. In these circumstances, we may be subject to significant enforcement actions. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could harm our business, financial condition and results of operations.

***Our products may be subject to recalls after receiving FDA approval or clearance, which could divert managerial and financial resources, harm our reputation and our business.***

The FDA has the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us

could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality-related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation and negatively impact our business.

If we initiate a correction or removal of one of our products to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports has been and could be used by competitors against us and could harm our reputation, which could cause customers to delay purchase decisions, cancel orders or decide not to purchase our products and could cause patients to lose trust in and decide not to implant our RNS System.

***If any of our products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, or MDRs, which can result in voluntary corrective actions or agency enforcement actions and harm our reputation, business, financial condition and results of operations.***

Under MDRs, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would be costly, distract management from operating our business, could be used by competitors against us, and may harm our reputation, business, financial condition and results of operations.

***From time to time, we engage outside parties to perform services related to certain of our clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to complete our clinical studies on our planned timelines, or at all, and may incur significant additional costs.***

From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage may interact with clinical investigators to enroll patients in our clinical studies. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, such as the FDA's Good Clinical Practice, or GCP, guidelines and FDA human subject protection regulations. We may face delays in completing our clinical studies if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical study protocols or for other reasons, our clinical studies or trials may need to be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs.

***Healthcare reform initiatives and other administrative and legislative proposals may harm our business, financial condition, results of operations and cash flows in our key markets.***

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could harm our business, financial condition and results of operations.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or

their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could harm our business, financial condition and results of operations.

***Our collection, use, storage, disclosure, transfer and other processing of sensitive and personal information could give rise to significant costs, liabilities and other risks, including as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices, which may harm our business, financial conditions, results of operations and prospects.***

In the course of our operations, we collect, use, store, disclose, transfer and otherwise process an increasing volume of sensitive, and personal information, including detailed recordings of iEEGs from patients as well as information from our employees and third parties with whom we conduct business. The collection, use, storage, disclosure, transfer and other processing of personal information is increasingly subject to a wide array of federal, state and foreign laws, rules, regulations, and standards regarding data privacy and security, including comprehensive laws of broad application, such as the CCPA and the GDPR, that are intended to protect the privacy of personal information that is collected, used, stored, disclosed, transferred or otherwise processed in or from the governing jurisdiction. As we seek to expand our business, we are, and may increasingly become, subject to various laws, rules, regulations and standards, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate or in the jurisdictions where our patients may be. When conducting clinical studies, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as GCP guidelines or FDA human subject protection regulations.

In many cases, these laws, rules, regulations and standards apply not only to third-party transactions, but also to transfers of information between or among us, any of our affiliates and other parties with whom we conduct business. These laws, rules, regulations and standards may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may harm our business, financial condition and results of operations. The regulatory framework for data privacy and security worldwide is continuously evolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

We are subject to many diverse laws and regulations relating to data privacy and security. In the United States, various federal and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Additionally, our customers may be subject to additional federal and state privacy and security laws, rules, regulations and standards, including HIPAA, that they may require us to comply

with through contractual obligations. This patchwork of legislation and regulation may give rise to conflicts or differing views of personal privacy rights. For example, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, foreign or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, the CCPA, which became effective on January 1, 2020, regulates the processing of personal information of California residents and increases the privacy and security obligations of covered companies handling such personal information. The CCPA requires covered companies to, amongst other things, provide new and additional disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to access their personal information and opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA and the CPRA, a consumer privacy ballot initiative that amends and expands the CCPA becomes effective on January 1, 2023. The CPRA affords California residents significantly more control over their personal information, imposes heightened compliance obligations on covered companies, and establishes a new enforcement agency dedicated to consumer privacy. Certain of CPRA's provisions impact personal information collected during the ramp-up period, on or after January 1, 2022. While aspects of the CPRA and its interpretation remain to be determined in practice, they create further uncertainty and may result in additional costs and expenses in an effort to comply. Further, all 50 states have passed laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected customers. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. We are also subject to the supervisory and enforcement authority of the Federal Trade Commission with regard to the collection, use, sharing, and disclosure of certain data collected from or about individuals. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which may harm our business, financial condition and results of operations.

In the event we expand our operations internationally, we may become subject to additional foreign data privacy and security laws, rules, regulations, requirements, and standards, which in the European Union, for instance, have been significantly reformed. On May 25, 2018, the GDPR entered into force and became directly applicable in all European Union member states. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires companies to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which companies can process personal data, makes it harder for companies to obtain valid consent for processing, requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the European Union, imposes additional obligations on companies when contracting with service providers and requires companies to adopt appropriate privacy governance including policies, procedures, training and data audits. The GDPR permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or four percent of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. If we become subject to the GDPR and do not comply with our obligations under the GDPR, we could be exposed to significant fines. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. In addition, we may be the subject of litigation or adverse publicity, which could negatively affect our business, financial condition and results of operations.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, rules, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation, scope, and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies or the features of our products and services. If so, in addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business, financial condition and results of operations. We may be unable to make such changes and modifications in a commercially reasonable manner, or at all. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with consumers and harm our business, financial condition and results of operations.

We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations.

Complying with these numerous, complex and often changing laws, rules, regulations, and standards is expensive and difficult. Any failure or perceived failure by us or our service providers to comply with our posted privacy policies or with any applicable or potentially applicable federal or state laws, rules, regulations, standards, certifications or orders relating to data privacy, security or consumer protection, or any compromise of security that results in the theft, unauthorized access, acquisition, use, disclosure, or misappropriation of personal information or other user data, could result in significant fines or penalties, negative publicity or proceedings or litigation by governmental agencies or consumers, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, penalties or judgments, one or all of which could require us to change our business practices or increase our costs and could materially and adversely affect our business, financial condition and results of operations. In addition, if our practices are not consistent, or viewed as not consistent, with applicable legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, all of which may harm our business, financial condition and results of operations.

***Significant disruptions in our information technology systems, whether through breaches or failures of our systems, unauthorized access or otherwise, may result in both an adverse impact to our products, as well as the unauthorized use, disclosure, modification or misappropriation of patient personal information, the occurrence of fraudulent activity, or other data security-related incidents, all of which could have a material and adverse impact on our business, financial condition and results of operations.***

We are increasingly dependent on complex information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing and inventory management purposes. Further, our products collect, use, store, disclose, transfer, and otherwise process sensitive patient data, such as detailed recordings of iEEGs to help clinicians make more informed treatment decisions and optimize their patients' care. These data are recorded by our RNS System and can be viewed by the physician during regular patient visits using the Physician Tablet or on

demand through a secure website. We also collect, use, store, disclose, transfer, and otherwise process a growing volume of other personal information and confidential, proprietary and sensitive data, which may include procedure-based information and sensitive healthcare data, credit card, and other financial information, insurance information, and other potentially personally identifiable information. Our information technology systems or those of our service providers may be subject to computer viruses, phishing, social engineering, denial or degradation of service attacks, ransomware, malware attacks or other threats, cyberattacks, or dishonest acts by computer hackers or terrorists, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. Technological interruptions or threats would disrupt our operations, including the ability of our clinicians to use our products as intended to treat patients, the ability of patients to safely and securely upload their data using and into our products, as well as our ability to adequately manufacture our products, timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. Additionally, any of these incidents could result in the theft, unauthorized access, acquisition, use, disclosure, modification, or misappropriation of personal information of patients that use our products, trial participants, employees, third parties with whom we conduct business, as well as other confidential, proprietary, and sensitive data, and can also result in fraudulent activity, system disruptions or shutdowns.

The occurrence of any actual or attempted breach, failure of security or fraudulent activity, the reporting of such an incident, whether accurate or not, or our failure to make adequate or timely disclosures to the public or law enforcement agencies following any such event, whether due to delayed discovery or a failure to follow existing protocols, could result in claims made against us or our service providers, which could result in state and/or federal litigation and related financial liabilities, as well as criminal penalties or civil liabilities, regulatory actions from state and/or federal governmental authorities, and significant fines, orders, sanctions, litigation and claims against us by consumers or third parties and related indemnification obligations. Actual or perceived security breaches or failures could also cause financial losses, increased costs, interruptions in the operations of our businesses, misappropriation of assets, significant damage to our brand and reputation with customers, patients, employees, and third parties with whom we do business, and result in adverse publicity, loss of consumer confidence, distraction to our management, and reduced sales and profits, any or all of which could harm our business, financial condition and results of operations.

Our systems are also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper actions by employees, service providers and other third parties with otherwise legitimate access to our systems and website. Data security-related incidents and fraudulent activity are increasing in frequency and evolving in nature. We rely on a framework of security processes, procedures, tools, and controls designed to protect our information and assets but, given the unpredictability of the timing, nature and scope of data security-related incidents and fraudulent activity, there can be no assurance that any security procedures and controls that we or our service providers have implemented will be sufficient to prevent data security-related incidents or other fraudulent activity from occurring. Furthermore, because the methods of attack and deception change frequently, are increasingly complex and sophisticated, and can originate from a wide variety of sources, including third parties such as service providers and even nation-state actors, despite our reasonable efforts to ensure the integrity of our systems and website, it is possible that we may not be able to anticipate, detect, appropriately react and respond to, or implement effective preventative measures against, all security breaches and failures and fraudulent activity. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner.

We also face risks associated with security breaches affecting third parties with whom we are affiliated or otherwise conduct business. Due to applicable laws and regulations or contractual obligations, we may be held responsible for any breach, failure or fraudulent activity attributed to our service providers as they relate to the information we share with them. In addition, while we take precautions in selecting service providers, because we do not control our service providers and our ability to monitor their data security is limited, we cannot ensure the security measures they take will be sufficient to protect our information. Any of the foregoing could harm our business, financial condition and results of operations.

As data security-related threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information

security vulnerabilities, or to protect against, respond to and recover from any potential, attempted, or existing security breaches. In addition, our remediation efforts may not be successful. The inability to implement, maintain and upgrade adequate safeguards could have a material and adverse impact on our business, financial condition and results of operations. Moreover, there could be public announcements regarding any data security-related incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our common stock. Any of the foregoing could harm our business, financial condition and results of operations.

We currently maintain a cybersecurity insurance policy and business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits, or will cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed. Therefore, failure to maintain or protect our information systems and data integrity effectively could harm our business, financial condition, and results of operations.

***We face potential liability related to the privacy of health information we obtain.***

We may maintain, use, and share sensitive health information that we receive directly from patients that use our products, throughout the clinical study process, in the course of our research collaborations, and from healthcare providers in the course of using our products and systems. Most healthcare providers, including hospitals from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive, maintain, use, or transfer individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, including certain health information, which is a broader class of information than the health information protected by HIPAA. To the extent we engage in clinical studies outside the United States, we may implicate foreign data privacy and security laws and regulations, including the GDPR and legislation of the European Union member states implementing it.

If we do business in international markets in the future, any failure by us or our third-party contractors to comply with the strict rules on the transfer of personal data outside of the European Union and the United Kingdom into the United States in accordance with such laws and regulations may result in the imposition of criminal and administrative sanctions on such contractors, which could adversely affect our business.

Moreover, patients about whom we or our contractors or collaborators obtain or share health information, as well as the providers who share this information with us or whom we share this data with, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could negatively affect our business, financial condition and results of operations. If we or third-party contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our products and could harm or prevent sales of our products, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Additionally, data collection, privacy and security have become the subject of increasing public concern and changing preferences towards data collection, privacy and security could adversely affect patient willingness to consent to our collection of their health information. Patients may be reluctant or unwilling to consent to the collecting of their health information, and patients that have opted-in to the collection of their health information may revoke their consent at any time, including as a result of these concerns or as a result of changes to our data policies that we have implemented or may implement in the future. In particular, the success of our business depends in part on our ability to lawfully obtain health information from our patients. If patients choose not to consent to the collection of their health information as a result of these concerns, or our consent practices are found to be unlawful, this could negatively impact the growth potential for our business.

***Compliance with environmental laws and regulations could be expensive, and the failure to comply with these laws and regulations could subject us to significant liability.***

Our research, development and manufacturing operations involve the use of hazardous substances, and we are subject to a variety of federal, state and local environmental laws and regulations relating to the storage, use, handling, generation, manufacture, treatment, discharge and disposal of hazardous substances. Our products may also contain hazardous substances, and they are subject laws and regulations relating to labeling requirements and to their sale, collection, recycling, treatment, storage and disposal. Compliance with these laws and regulations may be expensive and noncompliance could result in substantial fines and penalties. Environmental laws and regulations also impose liability for the remediation of releases of hazardous substances into the environment and for personal injuries resulting from exposure to hazardous substances, and they can give rise to substantial remediation costs and to third-party claims, including for property damage and personal injury. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence, and they tend to become more stringent over time, imposing greater compliance costs and increased risks and penalties associated with violations. We cannot be certain that violations of these laws and regulations, or releases of or exposure to hazardous substances, will not occur in the future or have not occurred in the past, including as a result of human error, accidents, equipment failure or other causes. The costs of complying with environmental laws and regulations, and liabilities that may be imposed for violating them, or for remediation obligations or responding to third-party claims, could negatively affect our business, financial condition and results of operations.

***Clinical studies may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to support label expansion for additional indications.***

We plan to continue to develop and execute clinical studies to support label retention for our products and label expansion for our products into additional epilepsy populations. We may also develop and execute clinical studies for new products or for label expansion for our current products into patient populations suffering from other neurologic conditions. We do not know whether future clinical studies will begin on time, need to be redesigned, enroll an adequate number of patients or be completed on schedule, if at all. The commencement and completion of clinical studies to support label retention and expansion for additional indications or for new products may be delayed, suspended or terminated as a result of many factors, including:

- the delay or refusal of regulators or Institutional Review Boards, or IRBs, to authorize us to commence a clinical study at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies, including due to COVID-19, and delays in or the inability to monitor enrolled patients, including due to COVID-19;
- the inability to enroll a sufficient number of patients in studies to observe statistically significant treatment effects in the trial;

- having clinical sites deviate from the trial protocol or dropping out of a study;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical studies;
- our CROs or clinical studies sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical study sites; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical studies.

We could also encounter delays if a clinical study is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such studies are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical study due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements, including GCP regulations, or our clinical protocols, inspection of the clinical study operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate safety and effectiveness, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical study.

In addition, we may encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical study site or the utility of the clinical study itself. Principal investigators for our clinical studies may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical study site may be questioned and the utility of the clinical study itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from supporting label retention and expansion for our RNS System.

**Risks related to our intellectual property**

***If we are unable to obtain, maintain, protect, enforce and defend patent or other intellectual property protection for our products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, or as a result of our existing or any future out-licenses of our intellectual property, our competitors could develop and commercialize products similar to or competitive with our products, our ability to continue to commercialize our RNS System, or our other products, may be harmed.***

As with other medical device companies, our success depends in large part on our ability to obtain, maintain, protect, enforce and defend a proprietary position for our products, which will depend upon our success in obtaining and maintaining effective patent and other intellectual property protection in the United States and other countries into which we may expand our business in the future that covers our RNS System and any other products, their manufacturing processes and their intended methods of use. Furthermore, our success will also depend on our ability to enforce and defend those patents, as well as our other intellectual property. In some cases, we may not be able to obtain patents covering our products which are sufficient to prevent third parties, such as our competitors, from utilizing our products, or our competitors may have rights under current or future out-licenses of our intellectual property, which could result in our competitors developing and commercializing products similar to or competitive with our products. Any failure to obtain, maintain, protect, enforce or defend patent and other intellectual property

protection with respect to our RNS System or other aspects of our business could harm our business, competitive position, financial condition and results of operations.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, protect, enforce, and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection in one, several, or all geographies. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. As such, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties, including by way of our cross-license with Medtronic, and we are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Furthermore, our license agreements may be terminated by the licensor. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like, although we are unaware of any such defects that we believe are of importance. If we or any of our current or future licensors or licensees fail to obtain, maintain, protect, enforce or defend such patents and other intellectual property rights, such rights may be reduced or eliminated. If any of our current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business.

The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions, can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our products, including our RNS System. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products, including our RNS System. Furthermore, even if they are unchallenged, our patents may not adequately protect our RNS System or any other products we develop, provide exclusivity for these products or prevent others from designing around our claims. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical products could be adversely affected. If the breadth or strength of protection provided by the patents we hold or

pursue with respect to our products is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future products, patents protecting such products might expire before or shortly after such products are commercialized. Our issued patents are expected to continue to expire through August 2038 without taking into account all possible patent term adjustments, extensions, or abandonments, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our RNS System or our other products will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner, which could harm our business, financial condition and results of operations.

Some of our patents and patent applications may be co-owned or cross-licensed with third parties. If we give up, do not pursue, or are unable to obtain an exclusive license to any such third-party co-owners' or licensee's interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our business, financial condition and results of operations.

***We may not be successful in obtaining necessary rights to any products or processes we may develop through acquisitions and in-licenses.***

We may find it necessary or prudent to acquire or obtain licenses to intellectual property or proprietary rights held by third parties that we may identify as necessary or important to our business operations. However, we may be unable to acquire or secure such licenses to any or all intellectual property or proprietary rights from third parties that we identify as necessary for our RNS System or any future products we may develop. The acquisition or licensing of third-party intellectual property or proprietary rights is a competitive area, and our competitors may pursue strategies to acquire or license third party intellectual property or proprietary rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third party intellectual property or proprietary rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully acquire or license required third-party intellectual property or proprietary rights or maintain the existing licenses to intellectual property rights we have, we may have to spend

time and resources to develop intellectual property ourselves or abandon development of the relevant product, both of which could harm our business, financial condition and results of operations.

***Patents covering our products, including our RNS System could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, which could harm our business, financial condition and results of operations.***

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or IPR, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense, would result in reputational harm, and would be a substantial diversion of employee resources from our business. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our products. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for the patents raised in such a claim. Such a loss of patent protection would harm our business, financial condition and results of operations.

***The medical device industry is characterized by patent litigation and in the future we could become subject to patent or other intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.***

Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends in part upon our ability and that of our suppliers to manufacture, market, sell, and use our proprietary products without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products. Additional third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. If we are found to infringe a third party's intellectual property rights, we could be required to incur costs to obtain a license from such third party to continue developing and marketing our products. We may also elect to enter into such a license in order to settle pending or

threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing product. In addition, we could be found liable for monetary damages, which may be significant. If we are found to have willfully infringed a third-party patent, we could be required to pay treble damages and attorneys' fees. A finding of infringement could prevent us from commercializing our planned products in commercially important territories, or force us to cease some of our business operations, which could harm our business and cause brand and reputational harm. We could also be forced to redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible. Many of our employees were previously employed at, and many of our current advisors and consultants are employed by, universities or other biotechnology, medical device, healthcare, or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Furthermore, although these agreements may be difficult to enforce, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, cause reputational harm, and could distract our technical and management personnel from their normal responsibilities. If we fail in defending any such claims, in addition to paying monetary damages or other settlements, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition and results of operations.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in the abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could harm our business, financial condition and results of operations.

***Certain of our patents are, and our future owned and in-licensed patents may be, discovered through government funded programs and thus may subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.***

Certain of our patents are, and our future owned and in-licensed patents may be, discovered through government funded programs. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act, and implementing regulations, which are amended from time to time. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, which are also referred to as "march-in rights." The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under or in collaboration with a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our future ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may permit the U.S. government to disclose our confidential information to third parties. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of any of the foregoing rights could harm our business, financial condition, results of operations and prospects.

***If we fail to comply with our obligations in any current or future agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We are and may become party to license or collaboration agreements with third parties to advance our research or allow commercialization of our products. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise certain efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our products, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours. We may further be required to cease our development and commercialization of certain of our products. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our sales, business, financial condition or results of operations. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected products, which could have a material adverse effect on our sales, business, financial conditions or results of operations.

***If we are unable to obtain patent term extension under the Hatch-Waxman Amendments, our business may be materially harmed.***

Depending upon the timing, duration and specifics of FDA marketing approval of our products, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, even if, at the relevant time, we have an issued patent covering our product, we may not be granted an extension if we were, for example, to fail to exercise due diligence during the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope of patent protection afforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may obtain approval of competing products following our patent expiration. As a result, our ability to generate revenues could be adversely affected. Further, if this occurs, our competitors may take advantage of our investment in development and studies by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If we do not have adequate patent protection or other exclusivity for our products, our business, financial condition or results of operations could be adversely affected**.**

***We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world, which could harm our business, financial condition and results of operations.***

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as in the United States. While we do not currently operate or sell our products outside of the United States, these products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries, which may impede on our ability to grow outside of the United States.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be harmed.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we could continue incurring costs without being certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Additionally, USPTO proceedings provide a venue for challenging the validity of patents at a cost must lower than district court litigation and on much faster timelines. This lower-cost, faster and potentially more potent tribunal for challenging patents could itself increase the likelihood that our own patents will be challenged. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects.

***We may be subject to claims, including third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators, challenging the ownership or inventorship of our intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of one or more of our products.***

The medical device industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, we may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. Additionally, we could become subject to significant intellectual property-related litigation and proceedings relating to our or third-party intellectual property and proprietary rights. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products, or could face third-party claims of intellectual property infringement, misappropriation or other violations, including by a licensor from whom we've licensed certain intellectual property.

Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our products. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition and results of operations.

Additionally, our commercial success depends in part on our and any potential future collaborators' ability to develop, manufacture, market and sell any products that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property or proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post-grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending patent applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. Unintentionally abandoned patents or applications can also be revived, so there may be recently revived patents or applications of which we are unaware. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, we may face claims from non-practicing entities, or NPEs, which have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Third parties, including NPEs, may in the future claim, that our products infringe or violate their patents or other intellectual property rights.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed by our products, which could harm our ability to commercialize any product we may develop and any other technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe third-party intellectual property rights, including patents, and we are unsuccessful in demonstrating that such patents or other intellectual property rights are invalid or unenforceable, such third parties may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay significant license fees and/or royalties, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same technology. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products and/or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such

intellectual property. Claims that we have misappropriated the confidential information or trade secrets of third parties could harm our business, financial condition and results of operations. We also might have to redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure.

Engaging in litigation, including to defend against third-party infringement claims is very expensive, particularly for a company of our size, and time-consuming. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition and results of operations.

***We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe our patents, or the patents of any current or future licensing partners, or we may be required to defend against claims of infringement. Our ability to enforce our patent rights against competitors who infringe our patents depends on our ability to detect such infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. For example, although we try to ensure that our employees, consultants and advisors are not in breach of any past contractual obligations and do not use the proprietary information or know-how of others in the work that they do for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their former university or employer. Additionally, we may be subject to claims from third parties challenging intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to a previous employer, or to another person or entity. Furthermore, while it is our policy to require all employees and contractors to execute agreements assigning relevant intellectual property to us, we may also be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. These assignment agreements may not be self-executing or adequate in scope, and may be breached or challenged, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not have adequate remedies for any such breaches, and such claims could harm our business, financial condition and results of operations.

To counter or defend against such claims can be expensive and time-consuming and it may be necessary or we may desire to enter into a license to settle any such claims; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. In an infringement proceeding, a court may decide that our patent is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace, including ability to hire new employees or contract with independent sales representatives. Additionally, we may lose valuable intellectual property rights or personnel. Any of the foregoing could harm our business, financial condition and results of operations.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be harmed.***

Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build or sustain name recognition among potential partners, customers and patients in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to continue to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, domain names or other intellectual property, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs, diversion of resources, or adverse impact to our brand and could harm our business, financial condition and results of operations.

***Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition and results of operations.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, may evolve, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- our intellectual property strategy may be limited, we may not seek protection for intellectual property that may ultimately become relevant to our business or our invention disclosure process may prove insufficient to encourage inventors to come forward with protectable intellectual property;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our current or future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- it is possible that our patents or patent applications omit individuals that should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- the claims of our patents or patent applications, if and when issued, may not cover our products or technologies;
- the laws of foreign countries may not protect our proprietary rights or the rights of current or future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could harm our business, financial condition and results of operations.

***If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and other confidential or proprietary information that is not patentable or that we elect not to patent. However, such information can be difficult to protect, and some courts, for instance, are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators, suppliers, customers, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Furthermore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection or equitable remedies for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such

third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights have or will be adequate. Trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to foreign markets or require costly efforts to protect our products.

We also license rights to use certain proprietary information and technology from third parties. The use of such proprietary information and technology is therefore subject to the obligations of the applicable license agreement between us and the owner. For example, the software we developed for our RNS System includes the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. The owner of any such proprietary information or technology also might not enforce or otherwise protect its rights in the proprietary information or technology with the same vigilance that we would, which would allow competitors to use such proprietary information and technology without having to adhere to a license agreement with the owner.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar products or technology. Our competitors could purchase our products and attempt to reverse engineer or replicate some or all of the competitive advantages we derive from our development efforts or design around our protected products or technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products, substantially and adversely impact our sales and commercial operations and harm our business. Additionally, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Further, it is possible that others will independently develop the same or similar technology or product or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors otherwise obtain our trade secrets or independently develop technology or products similar to and potentially competing with our products, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, systems and tools, agreements or security measures may be breached, whereby detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

***Our inability to use software licensed from third parties, or our use of open source software under license terms that interfere with our proprietary rights, could disrupt our business.***

Our products, including our RNS System, includes the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. Although we monitor our use of open source software, the terms of many open source licenses to which we are

subject have not been interpreted by U.S. or foreign courts, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to provide our technology to our customers. Moreover, we cannot ensure that we have not incorporated additional open source software in our products in a manner that is inconsistent with the terms of the applicable license or our current policies and procedures. In the future, we could be required to seek licenses from third parties in order to continue offering our solutions, which licenses may not be available on terms that are acceptable to us, or at all. Claims related to our use of open source software could also result in litigation, require us to purchase costly licenses or require us to devote additional research and development resources to change the software underlying our technology, any of which would have a negative effect on our business, financial condition and operating results and may not be possible in a timely manner. We and our customers may also be subject to suits by parties claiming infringement due to the reliance by our products on certain open source software, and such litigation could be costly for us to defend or subject us to injunctions enjoining us from the sale of our products that contain open source software.

Alternatively, we may need to re-engineer our products or discontinue using portions of the functionality provided by our products. In addition, the terms of open source software licenses may require us to provide software that we develop using such software to others on unfavorable terms, such as by precluding us from charging license fees, requiring us to disclose our source code, requiring us to license certain of our own source code under the terms of the applicable open source license or requiring us to provide notice on our products using such code. Any such restriction on the use of our own software, or our inability to use open source or third-party software, could result in disruptions to our business or operations, or delays in our development of future products or enhancements of our existing products, such as our RNS System, which could impair our business.

**Risks related to financial matters**

***We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we do achieve profitability, we may not be able to sustain it.***

We have incurred losses since our inception and expect to continue to incur losses for the foreseeable future. For the nine months ended September 30, 2022 and 2021, we reported net losses of $35.9 million and $25.4 million, respectively. As a result of these losses, as of September 30, 2022, we had an accumulated deficit of approximately $459.7 million. We expect to continue to incur significant business expenses as we continue to enhance our efforts to promote our brand, increase sales, improve therapy effectiveness, enhance the patient and provider experience, and expand the population of eligible patients. In addition, we expect our selling, general and administrative expenses to increase as we continue to operate as a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue and improve our gross margins in order to achieve and sustain profitability. It is possible that we will not achieve profitability or that, even if we do achieve profitability, we may not remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

Our expected future capital requirements may and do depend on many factors including expanding our customer base, the expansion of our sales force, our efforts to manage our expenses, and the timing and extent of spending on updating our product to enhance our offering or expand our reach. We may need additional funding to fund our operations but additional funds may not be available to us on acceptable terms on a timely basis, if at all. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay any dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation or asset sale transactions. Any future debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs, which will likely harm our ability to execute on our business plan and continue operations.

***We are party to an existing Term Loan Agreement, which contains restrictive covenants as well as financial maintenance covenants, and if we are unable to comply with these covenants then the lenders could declare an event of default wherein we may need to immediately repay the amounts due under the Term Loan Agreement.***

In September 2020, we entered into a Term Loan Agreement, or the Term Loan, pursuant to which the lender has made available to us an aggregate principal amount not to exceed $60.0 million, of which, as of September 30, 2022, we have drawn $50 million and the remainder was available to be drawn only if we met certain financial thresholds, which we did not meet. The Term Loan contains customary affirmative and restrictive covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to our holders, make investments, merge or consolidate with any other person or engage in transactions with our affiliates, as well as financial maintenance covenants, including minimum liquidity and annual revenue covenants. In March 2022, the Term Loan was amended to reduce the minimum annual revenue covenant. If we fail to comply with the covenants or payments specified in the Term Loan, the lenders could declare an event of default, which would give it the right to terminate its commitment to provide additional loans and declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, borrowings under the Term Loan are secured by substantially all of our properties, rights and assets, including intellectual property.

***To support our continued operations and the growth of our business, we may need to seek additional capital through new equity or debt financings, which sources of additional capital may not be available to us on acceptable terms or at all. If we are unable to obtain, if needed, adequate financing or financing on terms satisfactory to us, it could harm our business and growth prospects.***

Our operations have consumed substantial amounts of cash since inception and we intend to continue to make significant investments to support our continued business operations and growth, respond to business challenges or opportunities, enhance our products, expand the population of eligible patients, and potentially acquire complementary businesses and technologies. For the nine months ended September 30, 2022 and 2021, our net cash used in operating activities was $29.0 million and $16.4 million, respectively. As of September 30, 2022, we had $85.4 million of cash, cash equivalents and short-term investments and $9.4 million in current liabilities.

Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including our growth rate, the growth of sales and marketing teams and activities, our expense management initiatives, the expansion of the population of eligible patients, geographies we may choose to enter and commercialize in, updates to our products, potential introduction of new products, either developed internally or acquired, the continued oversight of regulatory agencies, and the continuing market acceptance of our products. Accordingly, we may need to engage in equity or debt financings or collaborative arrangements to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. In addition, during times of economic instability, it has been difficult for many companies to obtain financing in the public markets or to obtain debt financing, and we may not be able to obtain additional financing, if needed, on commercially reasonable terms, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us, if needed, it could harm our business and growth prospects.

***Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.***

In general, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. A Section 382 “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. As of December 31, 2021, we had $136.3 million of federal net operating loss

carryforwards and $115.2 million of state net operating loss carryforwards. The federal and state NOL carryforwards began expiring in 2022 and will additionally expire in 2028, for federal and state purposes, respectively. As of December 31, 2021, the amount of federal NOL carryforwards that does not expire is $83.1 million (subject to certain utilization limitations). We have conducted Section 382 studies and determined that we experienced ownership changes in 2016 and in 2021 which resulted in permanent limitation of our pre-change NOL and research and development credit carryforwards. In addition, future changes in our stock ownership, some of which are outside of our control, could result in an additional ownership change under Section 382 of the Code, further limiting our ability to utilize NOLs arising prior to such ownership change in the future. There is also a risk that due to statutory or regulatory changes, such as suspensions on the use of NOLs (including California legislation enacted in June 2020 that limited the ability to use California net operating losses to offset California income for tax years beginning after 2019 and before 2023), or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

***We previously identified and subsequently remediated a material weakness in our internal control over financial reporting. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations.***

We previously identified a material weakness in our internal control over financial reporting that had not been determined to be remediated as of December 31, 2021. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We did not design controls to address segregation of duties over the review and approval of account reconciliations and manual journal entries. There were no misstatements as a result of this material weakness; however, it could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

We implemented remediation steps in 2021 to improve our internal control over financial reporting, including hiring additional accounting personnel and implementing improved accounting and financial reporting procedures and controls. We have completed the design, testing and evaluation of new and enhanced internal controls and have determined that, as of September 30, 2022, the controls were designed and have operated effectively for a sufficient period of time for our management team to conclude that the material weakness has been remediated.

We cannot be certain that the actions we may take in the future will prevent or avoid potential future material weaknesses. If we identify any additional material weaknesses in our internal control over financial reporting and are unable to successfully remediate them , the accuracy and timing of our financial reporting may be negatively impacted, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result.

***Our history of recurring losses and anticipated expenditures as well as the significant amount of debt that we have incurred may affect our ability to operate our business and secure additional financing in the future.***

We have incurred operating losses to date and it is possible we may never generate a profit. Additionally, our obligations under the Term Loan Agreement are collateralized by substantially all of our assets, including our material intellectual property, and we are subject to customary financial and operating covenants limiting our ability to engage in various activities, which management may deem important for the business. The covenants related to the Term Loan Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. While we have not previously breached and are not currently in breach of these or any other covenants contained in our Term Loan Agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the term loan agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay

our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business.

**Other risks facing our company**

***The estimates of market opportunity and forecasts of market and revenue growth included in this Quarterly Report on Form 10-Q, including growth in the number of Level 4 CECs, epileptologists and neurosurgeons, as well as our projections related to the DIXI Medical distribution agreement, may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all.***

Market opportunity estimates and growth forecasts are subject to significant uncertainty. Our estimates of the annual total addressable markets for our RNS System are based on a number of internal and third-party estimates and assumptions, including, without limitation, our assumptions relative to the number of adults with drug-resistant focal epilepsy in the United States who are treated at Level 4 CECs each year; the number of neuromodulation procedures annually in the United States; the growth in number of Level 4 CECs, epileptologists, and neurosurgeons; the growth in number of patients referred to Level 4 CECs; and the potential growth of our market opportunity with the expansion of treatment to patients under age 18 and with drug-resistant generalized epilepsy patients. In addition, our projections related to becoming the exclusive U.S. distributor of DIXI Medical products are based on a number of estimates and assumptions, including, without limitation, information obtained from DIXI Medical related to historical performance and future projections. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of the COVID-19 pandemic, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our RNS System may prove to be incorrect. If the actual annual total addressable market for our RNS System is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. Alternatively, if the actual annual total addressable market for our RNS System is bigger than we have estimated, we may not be ready to manage such growth, which may impair our sales and have an adverse impact on our business.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm our business and our ability to sell our products, including our RNS System.***

We face an inherent risk of product liability as a result of the marketing and sale of our products. Although we have established internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we will eliminate or mitigate occurrences of these issues and associated liabilities. For example, we may be sued if our RNS System causes or is perceived to cause injury or is found to be otherwise unsuitable during manufacturing, marketing, sale, or distribution. Any such product liability claim may include, but not be limited to, allegations of defects in manufacturing, defects in design, defects in clinical study design or performance, a failure to warn of dangers inherent in the product, negligence, strict liability or a potential breach of implied or expressed warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on healthcare providers to determine appropriate patients for our products and to properly and correctly implant and use our RNS System as part of a patient's treatment protocol. If these healthcare providers are not properly trained, do not properly screen the patient, are negligent in implanting or using our RNS System or implant or use our RNS System "off-label," the capabilities or reputation of our RNS System may be diminished or the patient may suffer critical injury. While we believe that we clearly describe the limitations of our label, we cannot prevent an epileptologist from referring a patient for an RNS System implant for off-label indications, prevent a neurosurgeon from implanting our RNS System for off-label applications, or having our RNS System programmed based on off-label considerations. In addition, we cannot guarantee that healthcare providers are adequately trained prior to incorporating our RNS System into their practice. Complications resulting from the use of our products, including use of our RNS System off-label or use by healthcare providers who have not been trained appropriately, or at all, may expose us to product liability claims and

harm our reputation. We may also be subject to claims that are caused by the activities of our suppliers and vendors, such as those who provide us with components, materials, or services, which may have an impact on our products and result in product liability claims brought against us.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our brand or reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- increased insurance premiums;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to market and sell our products.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We currently carry product liability insurance in the amount of $7.0 million in the aggregate. In the future, we may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we may develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would harm our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our patient-focused brand, negatively impact our reputation in the industry, significantly increase our expenses and reduce product sales.

Some of our customers may also have difficulty in procuring or maintaining liability insurance to cover their operations, including their use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential additional customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

***The failure of third parties to meet their contractual, regulatory and other obligations could adversely affect our business.***

We rely on suppliers, vendors, partners, consultants, and other third parties to research, develop, and partake in both the manufacturing and commercialization of our products, as well as manage certain parts of our business. In addition, in August 2022 we entered into a distribution agreement with DIXI Medical pursuant to which we will become the exclusive U.S. distributor of DIXI Medical's product line, under which DIXI Medical will provide us

with ongoing commercial support and will supply us with DIXI Medical products, as ordered by us. Using these third parties poses a number of risks, such as:

- they may not perform to our standards or legal requirements;
- they may not produce reliable results;
- they may not perform in a timely manner;
- they may not maintain confidentiality of our proprietary information;
- disputes may arise with respect to ownership of rights to products developed with our partners; and
- disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration.

Moreover, some third parties may be located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory and other obligations may materially affect our business.

***Future legislation, potential changes in federal regulatory agency leadership, and new policies and priorities under the Biden Administration may adversely impact our company.***

Congress devoted substantial attention in 2021 to healthcare matters, through greater oversight of the FDA. Although the prospects for the imminent enactment of major legislation are not certain at this time, the enactment of more targeted measures may be more likely due to the increased possibility of bipartisan support for consideration of such measures. In addition, the Biden administration could impose new or modified COVID-19 programs and restrictions, and may propose additional fiscal or tax measures, or additional regulatory requirements that would apply to us or our customers, thereby impacting our business, operations and profitability. Moreover, changes in the leadership and senior staffs of the FDA could impact the rulemaking, supervision, examination and enforcement priorities and policies of the agency. The potential impact of changes in agency personnel, policies and priorities on the medical device sector, including us, cannot be predicted at this time.

In addition, the Biden administration has indicated an increased focus on enforcement of federal consumer protection laws and appoint consumer-oriented regulators. It is possible that regulators in the administration could promulgate rulemakings and bring enforcement actions that materially impact our business and the business of our customers. These regulators may, for example, augment requirements that apply to the medical device approval process, impose additional clinical studies requirements, or change privacy rules that impact how we maintain, use, and share sensitive healthcare data, and could otherwise revise or create new regulatory requirements that apply to us.

We may not be able to respond quickly or effectively to regulatory, legislative, and other developments, and these changes may in turn impair our ability to offer our current or planned products, or increase our cost of doing business. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, or criminal or civil sanctions, all of which may have an adverse effect on our reputation, business, financial condition and results of operations.

**Risks related to ownership of our common stock**

***If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.***

We may, from time to time, issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter

into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

***We will continue to have broad discretion in the use of proceeds from our initial public offering and may invest or spend the proceeds in ways with which investors do not agree and in ways that may not yield a return.***

We will continue to have broad discretion over the use of proceeds from our initial public offering. Investors may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We currently are using or intend to use the net proceeds from our initial public offering to expand our sales and marketing efforts, increase our research and development activities, conduct or sponsor clinical studies, expand internationally, and provide for working capital and other general corporate purposes. We also used a portion of the net proceeds we received from our initial public offering to repay approximately $4.0 million of principal indebtedness, plus accrued interest, under our Paycheck Protection Program loan. Our failure to apply the net proceeds of our initial public offering effectively could impair our ability to pursue our growth strategy or could require us to raise additional capital. In addition, pending their use, the proceeds of our initial public offering may have been or could be placed in investments which may not produce income or that may lose value.

***Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to decline.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

As of September 30, 2022, we had a total of approximately 24,864,119 shares outstanding of common stock, of which 6,658,364 shares are held by directors, executive officers and other affiliates. These shares will be subject to volume limitations under Rule 144 under the Securities Act, and may also be subject to vesting requirements.

As of September 30, 2022, there were approximately 7,279,578 shares of common stock subject to outstanding stock options and restricted stock units (RSUs) or reserved for future issuance under our equity incentive plans. All of the shares of common stock issuable upon exercise of outstanding stock options, vesting and settlement of RSUs, and exercise of settlement of any options or other equity incentives are registered for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements, subject to the lock-up agreements and, for our affiliates, volume limitations described above.

In addition, certain of our stockholders have registration rights that would require us to file registration statements for the public resale of the common stock issuable upon conversion of such shares or to include such shares in registration statements that we may file on our behalf or for other stockholders.

***Concentration of ownership of our common stock among our executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Based on the number of shares of common stock outstanding as of September 30, 2022, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own, including through the right to acquire within sixty days, approximately 75.3% of our common stock. These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders and they may want us to pursue strategies that deviate from the interests of other stockholders.

***We are an emerging growth company and a smaller reporting company, and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Quarterly Report on Form 10-Q and our periodic reports and proxy statements.

We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the first fiscal year after our annual gross revenues exceed $1.07 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.00 billion in non-convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year.

Anti-takeover provisions in our charter and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management without the consent of our board of directors. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- provide for a classified board of directors whose members serve staggered terms;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated convertible preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed for cause only upon the vote of the holders of at least 66 2/3% of our outstanding shares of common stock;

- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least 66 2/3% of our outstanding shares of common stock entitled to vote at an election of directors to adopt, to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware or, under certain circumstances, the federal district courts of the United States of America be the exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

These provisions do not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States of America have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our amended and restated certificate of incorporation, including those described in the preceding sentences.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provide that the federal district courts of the United States be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of

incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could harm our business, financial condition, results of operations, and prospects.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business and financial condition.

**General risk factors**

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics or pandemics, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Our ability to obtain components for our products could be disrupted if the operations of our suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters and manufacturing facility is located in Mountain View, California, near major earthquake faults and fire zones. Should our facilities be significantly damaged or destroyed, it could take months to relocate or rebuild, during which time our manufacturing would cease or be delayed and our RNS System may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and approval of a PMA supplement. Because of the time required to authorize manufacturing in a new facility under FDA regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and, to some extent, lost revenue, but not general damage or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facility could harm our business, financial condition, and results of operations.

Further, our operations could be disrupted by tariffs, international conflict or war. For example, in late February 2022, Russia initiated significant military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia, and the United States and certain other countries could impose further sanctions, trade restrictions and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions that may be taken by the United States and other countries in respect thereof, as well as any counter measures or retaliatory actions by Russia in response. Such conflict may cause regional instability, geopolitical shifts and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. In particular, while it is difficult to anticipate the impact of any of the foregoing on us, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition and results of operations.

***Litigation and other legal proceedings may harm our business.***

We are involved in, and from time to time in the future we may become involved in, legal proceedings relating to patent and other intellectual property matters, product liability claims, employee matters, tort or contract claims,

federal regulatory investigations, private rights of action, securities matters and class actions as well as other legal proceedings or investigations, which could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, on April 20, 2021, we received correspondence from the United States Department of Treasury regarding an inquiry into a matter that may fall under the jurisdiction of the Committee on Foreign Investment in the United States, or CFIUS. While we believe that our RNS System is not a critical technology for which CFIUS would have jurisdiction and does not pose a national security risk, we are cooperating fully with CFIUS on the matter. In addition, on October 18, 2021, three of our stockholders, James Jacoby, George Vachtsevanos, and Javier Echauz, filed a complaint in the United States District Court for the Northern District of California, entitled *James Jacoby et al. v. NeuroPace, Inc., et al.*, Case No. 3:21-cv-8136, against us and our board of directors. The complaint alleges various claims related to our reverse stock splits and seeks, among other relief, damages and attorney's fees. The complaint was amended on December 28, 2021 to name additional defendants. On August 8, 2022, we entered into a confidential settlement agreement, which contains, among other things, a mutual release of claims and no admission of liability by us or our board of directors. On August 9, 2022, the Parties filed a stipulation of dismissal with prejudice, which was entered by the Court on August 9, 2022.

Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts, judgements, and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. We may fail to enter into settlements or to obtain rulings for matters we believe we have resolved. There may be an increase in the scope of these or other matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us, irrespective of outcome, could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

***Our stock price may be volatile, an active or liquid market in our common stock may not be sustainable and the value of our common stock may decline.***

An active or liquid market in our common stock may not be sustainable and the market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- actual or anticipated fluctuations in our financial condition and results of operations;
- variance in our financial performance from expectations of securities analysts or investors;
- changes in the coverage decisions, reimbursement or pricing of our products;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our products;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- publicity associated with issues related to our products;
- our involvement in regulatory investigations or litigation;
- future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- the trading volume of our common stock;

- changes in the anticipated future size and growth rate of our market;
- general economic, regulatory, and market conditions, including economic recessions or slowdowns;
- the impact of the COVID-19 pandemic;
- changes in the structure of healthcare payment systems; and
- developments or disputes concerning our intellectual property or other proprietary rights.

Broad market and industry fluctuations, as well as general economic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small public float of shares of our common stock on the Nasdaq Global Market, the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our reputation and our business.

***If securities or industry analysts do not continue to publish research or publish unfavorable or inaccurate research about our business, our common stock price and trading volume could decline.***

Our stock price and trading volume will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not continue to publish research or reports about our business, delay publishing reports about our business or publish negative or unfavorable reports about our business, regardless of accuracy, our common stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We expect that only a limited number of analysts will cover our company and we do not have any control over these analysts. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline.

Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our reputation may be adversely impacted and our stock price would likely decline.

***We are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to maintain the adequacy of these internal controls may negatively impact investor confidence in our company and, as a result, the value of our common stock.***

We are required pursuant to Section 404 of the Sarbanes-Oxley Act to include in our annual reports, the first of which being for the year ending December 31, 2022, a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the Securities and Exchange Commission, or the SEC, following the date we are no longer an emerging growth company. We have not yet commenced the costly and challenging process of compiling the system and process documentation necessary to perform the evaluation required under Section 404. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and

compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if we identify additional material weaknesses in our internal control over financial reporting, our reputation could be negatively impacted, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, we could be subject to sanctions or investigations by the Nasdaq Global Market, the SEC or other regulatory authorities and our access to the capital markets could be restricted in the future.

***Our operating results may fluctuate across periods, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.***

Our quarterly and annual operating results may fluctuate across periods, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our products and any future products, which may vary significantly from period to period;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the timing and cost of obtaining regulatory approvals or clearances to expand our indications and get future approvals of any future products or features;
- pricing pressures;
- our ability to expand the geographic reach of our commercial efforts;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to our products, and potential future products that compete with our products;
- the timing and success or failure of preclinical or clinical studies for expanding the indications of our RNS System or any future products we develop or competing products;
- positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry;
- the timing of customer orders or scheduling of implants using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, vacations, the mix of products sold and the geographic mix of where products are sold, including any related foreign currency impact;
- the impact of COVID-19 on procedure volume or otherwise;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be

meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it could harm our business, financial condition, and results or operations.

***We will continue to incur increased costs as a result of operating as a public company, and our management and board of directors will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.***

As a public company, we will continue to incur significant legal, accounting, and other expenses. We expect such expenses to further increase after we are no longer an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, most senior members of our management team as well as our board of directors do not have significant experience with operating a public company. As a result, our management, board of directors, and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will drive high legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of these additional costs or the timing of such costs.

***We may become subject to numerous laws and regulations related to anti-bribery and anti-corruption laws, such as the FCPA and the U.K. Bribery Act, in which violations of these laws could result in substantial penalties and prosecution.***

We currently do not market and sell our products outside the United States. However, if we choose to conduct business outside the United States, our business will be subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the FCPA and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third-party business partners and intermediaries, fail to comply with the FCPA or other anti-corruption and anti-bribery laws. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, we may have to incur substantial costs to enhance our controls if we begin doing business outside the United States, and even so, such compliance measures ultimately may not be effective in prohibiting our employees, contractors, business partners, intermediaries or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation may result in a significant diversion of management’s attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery, anti-corruption or anti-money laundering laws to which we become subject could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could harm our business, financial condition and results of operations.

***We may acquire other businesses, which could require significant management attention, disrupt our business, dilute stockholder value and harm our results of operations.***

As part of our business strategy, we may in the future make acquisitions or investments in complementary companies, products or technologies that we believe fit within our business model and can address the needs of our customers and the patients they serve. In the future, we may not be able to acquire and integrate other companies, products or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions in an appropriate timeframe and on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur

additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by management, as well as our employees, customers, investors and industry analysts.

Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be harmed by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, one-time charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations.

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

***Unregistered Sales of Equity Securities***

None.

***Use of Proceeds***

In April 2021, we closed our initial public offering of 6,900,000 shares of our common stock, including shares issued upon the exercise in full of the underwriters' option to purchase 900,000 additional shares of common stock, at a public offering price of $17.00 per share. We received gross proceeds of $117.3 million. All of the shares issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-254663), which was declared effective by the SEC on April 21, 2021. J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC acted as joint lead book-running managers for the offering. Wells Fargo Securities, LLC and SVB Leerink LLC also acted as book-running managers for the offering. Shares of our common stock began trading on the Nasdaq Global Market on April 22, 2021 and, following the sale of all the shares upon the closing of the initial public offering on April 26, 2021, the offer terminated.

The net proceeds to us after deducting underwriting discounts and commissions of $8.2 million and net offering expenses of approximately $3.6 million were $105.5 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of proceeds from our initial public offering from those disclosed in the final prospectus for our initial public offering dated as of April 21, 2021 and filed with the SEC pursuant to Rule 424(b)(4) on April 23, 2021.

***Issuer Purchases of Equity Securities***

None.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

In August 2011, we entered into a non-cancelable operating lease for combined office and manufacturing facilities in Mountain View, California, which was amended in May 2018 to extend it through June 2024. In August 2022, we entered into a second amendment to the lease to extend the lease for six years through June 30, 2030 (from June 30, 2024). The second amendment contains a rent-free period from September 1, 2022 through December 31, 2022. Under the lease amendment, our option to extend the lease for a period of five years changed from commencing on July 1, 2024 and expiring on June 30, 2029, to commencing on July 1, 2030 and expiring on June 30, 2035.

**Item 6. Exhibits**

| Exhibit Number | Description of Exhibit | Incorporation by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Form | File Number | Exhibit | Filing Date | |
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect. | 8-K | 001-40377 | 3.1 | April 26, 2021 | |
| 3.2 | Amended and Restated Bylaws of the Registrant, as currently in effect | S-1/A | 333-254663 | 3.4 | April 14, 2021 | |
| 4.1 | Form of common stock certificate of the Registrant. | S-1/A | 333-254663 | 4.1 | April 14, 2021 | |
| 10.1 | Amended and Restated Investors' Rights Agreement, dated August 19, 2020, by and among the Registrant and the investors listed on Exhibit A thereto | S-1/A | 333-254663 | 10.1 | April 14, 2021 | |
| 10.2 | Second Amendment to Office Lease, dated August 22, 2022, by and between the Company and BXP Research Park LP (f/k/a BP MV Research Park LLC). | | | | | X |
| 10.3+ | Exclusive Distribution Agreement, dated August 9, 2022, by and between the Company and DIXI Medical USA Corp. | | | | | X |
| 31.1 | Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 31.2 | Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32.1* | Certification of Principal Executive Officer and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 101.INS | Inline XBLR Instance Document - the instance document does not appear in the Interactive Data File because its XBLR tags are embedded within the Inline XBLR document. | | | | | |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. | | | | | X |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. | | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | | X |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | | X |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document. | | | | | X |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibits 101) | | | | | X |

* The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Quarterly Report on Form 10-Q and is not deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, irrespective of any general incorporation language contained in such filing.

+ Portions of this exhibit (indicated by [*]) have been omitted because the registrant has determined that the information is both not material and is the type that the registrant treats as private or confidential.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mountain View, State of California, on November 8, 2022.

**NEUROPACE, INC.**

By: /s/ Michael Favet

Michael Favet
President and Chief Executive Officer

By: /s/ Rebecca Kuhn

Rebecca Kuhn
Chief Financial Officer and Vice President, Finance and Administration
(Principal Financial and Accounting Officer)

**455 NORTH BERNARDO AVENUE**

**SECOND AMENDMENT TO OFFICE LEASE**

THIS SECOND AMENDMENT TO OFFICE LEASE (this "**Second Amendment**") is made and entered into as of August 22, 2022 by and between **BXP RESEARCH PARK LP**, a Delaware limited partnership ("**Landlord**"), and NEUROPACE, INC., a Delaware corporation ("**Tenant**").

R E C I T A L S

A. Landlord and Tenant entered into that certain Office Lease dated August 24, 2011, as amended by that certain First Amendment to Office Lease dated as of May 24, 2018, and as amended by that certain Lease Modification Agreement dated as of April 30, 2020 (as amended, the "**Original Lease**"), whereby Landlord leased to Tenant, and Tenant leased from Landlord a total of 52,528 rentable square feet of space (the "**Premises**"), located in that certain building located at 455 North Bernardo Avenue in Mountain View, California (the "**Building**"), as more particularly described in the Lease.

B. Landlord and Tenant desire to: (i) renew the term of the Lease commencing on September 1, 2022 and extend the term of the Lease for the Premises for a period of seven (7) years and ten (10) months from such date, and (ii) make certain other modifications to the Original Lease, and in connection therewith Landlord and Tenant desire to amend the Original Lease on the terms and conditions contained herein.

A G R E E M E N T

NOW THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Defined Terms**. All capitalized terms not otherwise defined herein shall have the same meaning as is given such terms in the Original Lease. From and after the date hereof, all references in the Original Lease and herein to the "Lease" shall mean and refer to the Original Lease, as amended hereby.

2. **Second Extended Term**. Landlord and Tenant acknowledge and agree that the Lease Term for the Premises is scheduled to expire on June 30, 2024 (the "**Scheduled Expiration Date**") pursuant to the terms of the Original Lease. Landlord and Tenant have agreed, notwithstanding the foregoing, to renew the term of the Lease so that the "**Second Extended Term**" shall commence on September 1, 2022 (the "**Second Extended Term Commencement Date**") and expire on June 30, 2030 (the "**Second Extended Term Expiration Date**"), unless sooner terminated or extended pursuant to the terms of the Lease. Effective upon the Second Extended Term Commencement Date, all references in the Lease to the "Term" or the "Lease Term" or the "Extended Term" shall mean and refer to the Extended Term, as extended by the Second Extended Term, where applicable.

3. **Option Term**. Landlord and Tenant agree that the renewal option granted to Tenant in Section 5 of the First Amendment is hereby terminated. In connection with this Second Amendment, Landlord hereby grants to the originally named Tenant on the Original

Lease and any Permitted Non-Transferee, one (1) option to extend the Second Extended Term for a period of five (5) years (the "**Option Term**"), on the terms set forth under Section 2.3 of the Original Lease, except that all references in such section to the "initial Lease Term" shall be deemed to mean the "Second Extended Term".

4. **Base Rent**. Notwithstanding anything to the contrary contained in the Original Lease, Section 3.1 of the First Amendment is hereby amended to provide that commencing on the Second Extended Term Commencement Date, and continuing throughout the Second Extended Term, Tenant shall pay Base Rent for the Premises in accordance with the following schedule:

| Period During Second Extended Term | Annual Base Rent | Monthly Installment of Base Rent |
|---|---|---|
| September 1, 2022 - December 31, 2023 | $2,773,478.40 | $231,123.20 |
| January 1, 2024 - December 31, 2024 | $2,856,682.75 | $238,056.90 |
| January 1, 2025 - December 31, 2025 | $2,942,383.23 | $245,198.60 |
| January 1, 2026 - December 31, 2026 | $3,030,654.73 | $252,554.56 |
| January 1, 2027 - December 31, 2027 | $3,121,574.37 | $260,131.20 |
| January 1, 2028 - December 31, 2028 | $3,215,221.60 | $267,935.13 |
| January 1, 2029 - December 31, 2029 | $3,311,678.25 | $275,973.19 |
| January 1, 2030 - June 30, 2030 | $3,411,028.60 | $284,252.38 |

5. **Abated Base Rent**. Provided that Tenant is not then in material or monetary default of the Lease beyond applicable notice and cure periods, then during the first four (4) full calendar months of the Second Extended Term (the "**Rent Abatement Period**"), Tenant shall not be obligated to pay any Base Rent otherwise attributable to the Premises during such Rent Abatement Period (the "**Rent Abatement**"). Landlord and Tenant acknowledge that the aggregate amount of the Rent Abatement equals $924,492.80 (the "**Abated Base Rent**"). Tenant acknowledges and agrees that the foregoing Rent Abatement has been granted to Tenant as additional consideration for entering into this Amendment, and for agreeing to pay the rental and performing the terms and conditions otherwise required under the Lease. If Tenant shall be in material or monetary default under the Lease and shall fail to cure such default within the notice and cure period, if any, permitted for cure pursuant to the Lease, and the Lease is terminated thereafter, then Landlord may at its option, by notice to Tenant, elect, in addition to any other remedies Landlord may have under the Lease, that Tenant shall immediately become obligated to pay to Landlord all unamortized Abated Base Rent (i.e., based upon the amortization of the Abated Base Rent in equal monthly amounts, without interest, during the period commencing on the Second Extended Term Commencement Date and ending on the Second Extended Term Expiration Date).

6. **Modification of Letter of Credit**. Landlord and Tenant acknowledge that, in accordance with Article 21 of the Lease, Landlord holds a Letter of Credit ("**Letter of Credit**") from Tenant in the amount of Two Hundred Forty-Four Thousand Two Hundred Fifty-Five and 00/100 Dollars ($244,255.00) as security for the faithful performance by Tenant of the terms, covenants and conditions of the Lease. In connection with this Second Amendment and effective

as of the Second Extended Term Commencement Date, Tenant shall deliver to Landlord an amended Letter of Credit, which amendment revises the Final Expiration Date of the Letter of Credit to the date that is one hundred twenty (120) days after the expiration of the Second Extended Term (the "**Final Expiration Date**").

7. **Condition of Premises**. Tenant hereby acknowledges that Tenant is currently in possession of the Premises and that neither Landlord nor any agent of Landlord has made any representation or warranty regarding the condition of the Premises, the Building or the Project, or with respect to the suitability of any of the foregoing for the conduct of Tenant's business. Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Premises, and Tenant shall continue to accept the Premises in its presently existing, "as-is" condition. Tenant hereby acknowledges and agrees that any improvements, alterations, additions or changes to the Premises (if any) performed by or on behalf of Tenant shall be completed pursuant to the terms and conditions of Article 8 of the Lease.

8. **Brokers**. Landlord and Tenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this Second Amendment and that they know of no real estate broker or agent, other than T3 Advisors / Savills (the "**Broker**"), who is entitled to a commission in connection with this Second Amendment, which commission shall be paid by Landlord pursuant to the terms of a separate written agreement between Landlord and Broker. Each party agrees to indemnify and defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments, and costs and expenses (including, without limitation, reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of any dealings with any real estate broker or agent, other than the Broker, occurring by, through, or under the indemnifying party. The terms of this Section 8 shall survive the expiration or earlier termination of the Original Lease, as amended by this Second Amendment.

9. **No Further Modification**. Except as specifically set forth in this Second Amendment, all of the terms and provisions of the Original Lease shall remain unmodified and in full force and effect. In the event of any conflict between the terms and conditions of the Lease, and the terms and conditions of this Second Amendment, the terms and conditions of this Second Amendment shall prevail.

10. **No Default**. Tenant represents, warrants and covenants to Landlord that, to Tenant's actual knowledge as of the date of this Second Amendment, Landlord is not in default of any of its obligations under the Original Lease and no event has occurred which, with the passage of time or the giving of notice, or both, would constitute a default by Landlord. As of the date hereof, to Tenant's actual knowledge, Tenant has no offsets, setoffs, rebates, concessions, claims or defenses against or with respect to the payment of Base Rent, Additional Rent or any other sums payable under the Lease, except as expressly provided in the Lease.

11. **Counterparts**. This Second Amendment may be executed in counterparts with the same effect as if both parties hereto had executed the same document. All counterparts shall be construed together and shall constitute a single agreement. The parties acknowledge and agree that they will accept faxed transmissions of, or electronically scanned and transmitted versions of, an original signature. In addition, the parties acknowledge and agree that they may conduct this transaction by electronic means and that this Amendment may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature.

12. **Authority**. Tenant hereby represents and warrants that Tenant is a duly formed and existing entity qualified to do business in California and that Tenant has full right and authority to execute and deliver this Second Amendment and that each person signing on behalf of Tenant is authorized to do so. Landlord hereby represents and warrants that Landlord is a duly formed and existing entity qualified to do business in California and that Landlord has full right and authority to execute and deliver this Amendment and that each person signing on behalf of Landlord is authorized to do so

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IN WITNESS WHEREOF, this Second Amendment has been executed as of the day and year on which the last signatory below executes this Second Amendment.

"**Landlord**":

**BXP RESEARCH PARK LP,**
a Delaware limited partnership

BY: BXP CALIFORNIA GP LLC,
a Delaware limited liability company,
its general partner

BY: BOSTON PROPERTIES LIMITED PARTNERSHIP,
a Delaware limited partnership,
its sole member

BY: BOSTON PROPERTIES, INC.,
a Delaware corporation,
its general partner

BY: */s/ Bob Pester*
Name: Bob Pester
Title: EVP

BY: BOSTON PROPERTIES LIMITED PARTNERSHIP,
a Delaware limited partnership,
its Series A Limited Partner

BY: BOSTON PROPERTIES, INC.,
a Delaware corporation,
its general partner

BY: */s/ Bob Pester*
Name: Bob Pester
Title: EVP

BY: BP/DC PROPERTIES, INC.,
a Maryland corporation,
its Series B Limited Partner

BY: */s/ Bob Pester*
Name: Bob Pester
Title: EVP

Date: 08/24/2022

"**Tenant**":

**NEUROPACE, INC.,**
a Delaware corporation

By: */s/ Rebecca Kuhn*
Name: Rebecca Kuhn
Title: CFO and Vice President
Date: 08/24/2022

By: */s/ Irina Ridley*
Name: Irina Ridley
Title: General Counsel
Date: 08/24/2022

EXECUTION VERSION

DIXI MEDICAL USA CORP

AND

NEUROPACE, INC.

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# EXCLUSIVE DISTRIBUTION AGREEMENT

EFFECTIVE AS OF: AUGUST 9, 2022

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**EXCLUSIVE DISTRIBUTION AGREEMENT**

This **EXCLUSIVE DISTRIBUTION AGREEMENT** (this "**Agreement**") effective as of August 9, 2022, (the "**Effective Date**"), is entered into by and between DIXI **Medical USA Corp**, a Delaware corporation, with its principal place of business located at 11910 Fox Ridge Dr., Plymouth, MI 48170 (the "**Company**") and **NeuroPace, Inc.**, a Delaware corporation with its principal place of business located at 455 Bernardo Ave., Mountain View, CA 94043 (the "**Distributor**"); each a "**Party**" and, together, the "**Parties**".

**RECITALS**:

(A) **WHEREAS**, Company develops and manufactures certain Products (as defined below).

(B) **WHEREAS**, Company desires to appoint Distributor as Company's exclusive distributor of the Products in the Field (as defined below) in the Territory (as defined below), and Distributor wishes to accept such appointment, in accordance with the terms and conditions of this Agreement.

**NOW, THEREFORE**, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. **DEFINITIONS AND INTERPRETATION**

1.1 Certain Definitions. For the purposes of this Agreement, the following terms have the following meanings:

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| "**1st Level Technical Support**" | means customer training, problem isolation and diagnosis, and a customer support hotline to address the foregoing; |
| "**2nd Level Technical Support**" | means support activities that Company deems reasonable to provide Distributor, at least at a level it provides to its other third party distributors, and consistent with past practice and industry standards. 2nd Level Technical Support excludes 1st Level Technical Support; |
| "**2022 List Price**" | has the meaning given in Clause 4.2; |
| "**Actual Exchange Rate**" | has the meaning given in Clause 4.5; |
| "**Affiliate**" | means with respect to a Person (including a Party), any entity that directly or indirectly controls, is controlled by or is under common control, with that Person. For purposes of this definition, "**control**" means direct or indirect beneficial ownership of more than fifty percent (50%) of the voting or income interest in such Person, or the power to control the management of such Person or direct its affairs or the distribution of its profits; |
| "**Agreement**" | has the meaning given in the preamble; |

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| "**Applicable Law**" | means, with respect to any Person, any federal, state, local, municipal, or other law, statute, principles of common law, ruling, legal requirement and standard, regulation, guidance, directive, constitution, treaty, convention, ordinance, code, rule, regulation, or order, enacted, adopted, promulgated or applied by a Governmental Authority, self-regulatory body, including, without limitation, GMP guidance, GDP guidance and QSR guidance, as may be amended from time to time, and any permits, licenses, approvals and authorizations having jurisdiction over or related to the Marketing Authorization, approval, marketing, promotion, distribution, storage and sale of the Products in the Territory or any part thereof; |
| "**Arbitration Notice**" | has the meaning given in Clause 17.2; |
| "**Arbitrator**" | has the meaning given in Clause 17.2; |
| "**Change of Control**" | means with respect to a Party, (a) a merger or consolidation of such Party with a third party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a third party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a third party of all or substantially all of such Party's and its controlled Affiliates' assets. For the avoidance of doubt, neither a transaction or series of transactions effected for the primary purpose of financing the operations of the applicable Party (including the issuance or sale of securities for financing purposes) or changing the form or jurisdiction of organization of such Party, nor a change in the control of a Party to the benefit of any Affiliate of such Party, shall constitute a Change of Control under this Agreement; |
| "**Claiming Party**" | has the meaning given in Clause 12.1; |
| "**Commercial Activities Effective Date**" | has the meaning given in Clause 6.1; |
| "**Commercial Support**" | means 2nd Level Technical Support solely provided during the Initial Term; |
| "**Commercial Support Requirements**" | has the meaning given in Clause 6.4; |
| "**Commercialization Plan**" | has the meaning given in Clause 6.3; |

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| "**Commercialize**" **or** "**Commercializing**" | means any and all activities directed to marketing, promoting, advertising, distributing, offering for sale, having sold and selling the Products in the Field in the Territory for commercial purposes. When used as a noun, "Commercialization" means any activities involved in Commercializing; |
| "**Company**" | has the meaning given in the preamble; |
| "**Company Indemnitee**" | has the meaning given in Clause 11.2; |
| "**Company IP**" | means any intellectual property rights in existence as of the Effective Date or thereafter during the Term that are Controlled by Company and necessary for the Commercialization of any of the Products in the Field in the Territory pursuant to this Agreement. For the avoidance of doubt, Company IP includes all Marks, Product IP, Feedback and Feedback-Related IP; |
| "**Confidential Information**" | means any and all non-public, technical, business or other information, or data of a Party or its Affiliates provided orally, visually, in writing, graphically, electronically, or in another form by or on behalf of such Party or its Affiliates to the other Party or its Affiliates in connection with this Agreement, including the terms of this Agreement, the Product, any exploitation of the Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates, or the scientific, regulatory or business affairs or other activities of the disclosing Party. For clarity, the existence and the terms of this Agreement are deemed Confidential Information of both Parties; |

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| "**Control or Controlled**" | means, with respect to any intellectual property rights, material or document, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense of or under such intellectual property rights, or to provide or provide access to such material or document, to the other Party without breaching the terms of any agreement with a third party; |
| "**Debarred/Excluded**" | means any Person becoming debarred or suspended under 21 U.S.C. §335(a) or (b), the subject of a conviction described in Section 306 of the FD&C Act, excluded, or having previously been excluded, from a federal or governmental health care program, debarred from federal contracting, convicted of or pled nolo contendere to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, the subject to Office of Foreign Assets Control ("**OFAC**") sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority; |
| "**Defective Product**" | has the meaning given in Clause 3.11.3; |
| "**Direct Competitor**" | means a company that manufactures and commercializes the same or substantially similar products to the Product; |
| "**Disputes**" | has the meaning given in Clause 17.1; |
| "**Disqualified**" | has the meaning given in Clause 10.3.8; |
| "**Distributor**" | has the meaning given in the preamble; |
| "**Distributor Indemnitee**" | has the meaning given in Clause 11.1; |
| "**Distributor Promotional Materials**" | has the meaning given in Clause 6.2.2; |
| "**Dollars**" **or** "**$**" | means the United States dollar, the lawful currency of the United States of America; |
| "**Effective Date**" | means the date on the cover page of this Agreement; |
| "**Euros or "€**" | means the single European currency; |
| "**Existing Recall**" | has the meaning given in Clause 5.10.2; |
| "**FD&C Act**" | means the United States Federal Food, Drug and Cosmetic Act, as amended; |

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| "**FDA**" | means the United States Food and Drug Administration and any successor entity thereto; |
| "**Feedback**" | has the meaning given in Clause 8.5; |
| "**Feedback-Related IP**" | has the meaning given in Clause 8.5; |
| "**Field**" | means any and all diagnosis or treatment of epilepsy in humans; |
| "**Force Majeure**" | has the meaning given in Clause 12.1; |
| "**Forecast**" | has the meaning given in Clause 3.4; |

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| "**Fully Loaded COGS**" | means, with respect to any Product supplied by or on behalf of Company to Distributor hereunder, the actual, fully-burdened cost to manufacture such Product, which means the actual unit costs of manufacture, which shall consist of direct material costs, direct labor costs, and manufacturing overhead attributable to such Product manufacturing activities, all calculated in accordance with GAAP. Direct material costs shall consist of the costs incurred in purchasing materials. Direct labor costs shall consist of the cost of: (a) employees working in manufacturing and packaging of the Product and employees working in facility maintenance; (b) the acquisition of third party manufacturing services; and (c) a fair and reasonable allocation of direct or indirect quality control and quality assurance activities and supply chain management, and including, in either case, any other costs required by GAAP. Manufacturing overhead specifically attributable to such Product shall include a reasonable allocation of administrative costs and a reasonable allocation of costs of equipment, utilities and manufacturing and distribution facilities used to manufacture the Product for Commercialization by Distributor. For clarity, Fully Loaded COGS shall exclude any costs associated with Company's provision of Commercial Support to Distributor hereunder in compliance with the Commercial Support Requirements as set forth in Clause 6.4, which shall be covered by the Upfront Payment under Clause 4.1; |
| "**GAAP**" | means United States Generally Accepted Accounting Principles; |
| "**GDP**" | means the then-current current Good Distribution Practices as promulgated in 21 C.F.R. § 820; |

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| "**GMP**" | means the then-current Good Manufacturing Practices as promulgated in 21 C.F.R. § 820 and Medical Device Quality System guides to the extent applicable to activities directly related to the manufacture of Product under this Agreement; |
| "**Governmental Authority**" | means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental, quasi-governmental or regulatory body of any nature, including any governmental division, department or agency; (d) court, arbitrator, arbitration panel, public tribunal or other body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power of any nature; or (e) any official of any of the foregoing authorities and bodies listed in this definition in his/her capacity as such; |
| "**Indemnification Claim Notice**" | has the meaning given in Clause 11.3.1; |
| "**Indemnified Party**" | has the meaning given in Clause 11.3.1; |
| "**Indemnifying Party**" | has the meaning given in Clause 11.3.1; " |
| **Initial Purchase Price**" | has the meaning given in Clause 4.2; |
| "**Initial Term**" | has the meaning given in Clause 14.1; |
| "**Latent Defect**" | has the meaning given in Clause 3.11.2; |
| "**Lead Time**" | has the meaning given in Clause 3.5.2; |
| "**List Price**" | has the meaning given in Clause 4.3; |
| "**Losses**" | has the meaning given in Clause 11.1; |

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| "**Marketing Authorization**" | means with respect to the Territory or to any part thereof, the approval(s), by the applicable Regulatory Authority, of the entire series of filings for marketing authorizations, permits, licenses, authorizations and notifications that, as per the Applicable Laws and regulations of the Territory or any part thereof, are required to finally and fully Commercialize the Product in the Territory or any part thereof, including any and all complement and supplement filings for marketing authorizations, permits, licenses, authorizations and notifications that are required to use and Commercialize the Product in the Territory or any part thereof. For clarity, Marketing Authorization does not include any pricing or reimbursement approvals; |
| "**Marks**" | has the meaning given in Clause 8.3; |
| "**Medical Device or Reporting**": **or** "**MDR**" | means the medical device reporting obligations as promulgated in 21 C.F.R. § 803; |
| "**Minimum Annual Order**" | has the meaning given in Clause 3.14; |
| "**Non-Claiming Party**" | has the meaning given in Clause 12.2; |
| "**Party(ies)**" | has the meaning given in the preamble; |
| "**Patent Defect**" | has the meaning given in Clause 3.11.1; |
| "**Permitted Subcontractor**" | has the meaning given in Clause 2.1.1; |
| "**Person**" | means any individual, corporation, partnership, limited liability company, firm, joint venture, association, trust, estate, unincorporated organization, Governmental Authority or other unnatural entity; |
| "**Product IP**" | has the meaning given in Clause 8.5; |
| "**Product Specifications**" | means those quality standards and specifications for the Products set forth in the QA Requirements Document; |

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| "**Products**" | means (a) All Company products currently approved for sale in the United States as of the Effective Date, as defined in the product list as set forth in the QA Requirements Document ("**Product List**"), (b) any modifications or improvements thereof made by Company during the Term and (c) any new Company products approved for sale in the United States during the Term, which shall be immediately added by Company to the Product List; |
| "**Purchase Order**" | has the meaning given in Clause 3.5.1; |
| "**Purchase Price**" | has the meaning given in Clause 4.3; |
| "**QA Requirements Document**" | means the Quality Requirements Document set forth in Appendix A attached hereto; |
| "**Quality System Regulations**" **or** "**QSR**" | means, with respect to the United States, the Quality System Regulations promulgated by the FDA and set forth in 21 C.F.R. § 820, and which describe the minimum requirements for the methods, facilities and controls used in the manufacturing, processing, packaging or holding of a medical device; |
| "**Quarter**" | means each period of three months ending on March 31st, June 30th, September 30th, and December 31st; |
| "**Recall**" | means (a) a recall, withdrawal, or field correction of any Product purchased by Distributor in the Territory or (b) a dissemination of relevant information regarding such a Product due to a safety or efficacy issue, in each case of (a) or (b), either (i) required or ordered by a Regulatory Authority of competent jurisdiction, or if any Regulatory Authority requires or advises Distributor or any of its Permitted Subcontractors to distribute a "**Dear Doctor**" letter or its equivalent regarding use of such Product in the Territory, (ii) if Company determines that a recall of any Product is appropriate, or (iii) if a recall is determined, in good faith, by Distributor as reasonably necessary; |
| "**Regulatory Authority**" | means any competent authority or agency within the Territory, responsible for the grant of Marketing Authorization or that regulates the importation, distribution, commercialization or sale of, or pricing or reimbursement for, the Product in the Territory or any part thereof; |
| "**Renewal Term**" | has the meaning given in Clause 14.1; |

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| "**Senior Officer**" | means the officer of each Party designated by each Party to the other in writing, or any direct report of such officer designated by such officer as a Senior Officer hereunder who has authority to resolve the matter in dispute hereunder; |
| "**Shortfall**" | has the meaning given in Clause 3.13; |
| "**Subcontracting Agreement**" | has the meaning given in Clause 2.1.1; |
| "**Tax Deductions**" | has the meaning given in Clause 4.8; |
| "**Term**" | means the term of this Agreement as set out in Clause 14.1; |
| "**Territory**" | means United States, including its territories and possessions, and excludes all other countries and territories; and |
| "**Upfront Payment**" | has the meaning given in Clause 4.1. |

1.2 Interpretation. In this Agreement:

1.2.1 the headings are inserted for convenience only and do not affect the construction of this Agreement;

1.2.2 references to one gender includes both genders and references to the singular include the plural and vice versa;

1.2.3 references to clauses and Schedules are to clauses of, and schedules to, this Agreement;

1.2.4 references to "days" in this Agreement shall mean calendar days, unless otherwise specified;

1.2.5 where this Agreement uses the term "including" it shall mean "including without limitation";

1.2.6 where this Agreement uses the term "will" it shall be construed to have the same meaning and effect as the word "shall" wherever context requires; any agreement or instrument defined or referred to herein, or in any agreement or instrument that is referred to herein, means such agreement or instrument as from time to time amended, modified or supplemented;

1.2.7 any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted;

1.2.8 references in this Agreement to a Party's awareness or knowledge of any fact or circumstances shall mean that Party's actual awareness or knowledge, without having conducted any searches or investigations; and

1.2.9 where this Agreement provides for any right or remedy, such right or remedy shall be without prejudice to any other right or remedy that may be available by law or in equity.

1.3 Any Schedules and Appendices attached hereto shall comprise part of and shall be construed in accordance with the terms of this Agreement. In the event of any inconsistency between the Schedules (or the Appendices) and the terms of this Agreement, the terms of this Agreement shall prevail.

## 2. APPOINTMENT OF DISTRIBUTOR

2.1 Appointment. Company hereby appoints Distributor as its sole and exclusive distributor to Commercialize the Products in the Field in the Territory, and Distributor hereby accepts such appointment and agrees to act as the exclusive distributor of the Products in the Field in the Territory.

2.1.1 Subcontracting. Distributor shall not have the right to appoint, sublicense or otherwise transfer its rights and obligations hereunder to any Affiliate, representative, sub-distributor, agent or third party (including a third party logistics provider) without Company's prior written consent, provided that Distributor shall have the right to subcontract without Company's prior written consent to its Affiliates, or to a third party, discrete support services in connection with Distributor's obligations under this Agreement, including, by way of an example, for the purposes of marketing and accounting (collectively, "**Permitted Subcontractor**"). Any agreement pursuant to which Distributor engages any Permitted Subcontractor ("**Subcontracting Agreement**") must be consistent with the terms of this Agreement, including containing obligations of confidentiality and non-use at least as stringent as those set forth in Clause 9, and obligations to assign to Distributor all intellectual property generated by such Permitted Subcontractor in the course of performing such subcontracted work, consistent with the intellectual property provisions set forth in Clause 8. Distributor retains responsibility for the acts and omissions of its Permitted Subcontractors in relation to the Product as if they were the acts and omissions of Distributor itself, and shall remain responsible for any obligations that have been delegated or subcontracted to any Permitted Subcontractor and for the performance of its Permitted Subcontractors. Without limiting the generality of the foregoing, each Subcontracting Agreement must include an assignment back to Distributor of all intellectual property developed, invented, or filed (as applicable) by or on behalf of the Permitted Subcontractor under such agreement (such that Distributor Controls such intellectual property for the purposes of this Agreement). Any Permitted Subcontractor which is Debarred/Excluded shall automatically cease to be an Permitted Subcontractor. Promptly upon execution of each Subcontracting Agreement (and in any event, prior to a Permitted Subcontractor performing any activities on behalf of Distributor), Distributor must provide to Company the contact information for such Permitted Subcontractor.

2.2 Exclusivity.

2.2.1 Company. Company shall not (a) Commercialize or otherwise provide the Products to any Person other than Distributor within the Field in the Territory, or (b) authorize or permit any Person other than Distributor to Commercialize the Products within the Field in the Territory.

2.2.2 Distributor. Distributor shall purchase its entire requirement for the Products only from Company or its Affiliates. Distributor covenants and agrees that it shall not, and shall ensure that its Permitted Subcontractors do not, either directly or indirectly, Commercialize any Products, including via the Internet or mail order, to any Person or to any address or Internet Protocol address, or the like, in each case, outside the Territory. Distributor shall not engage, and shall ensure that its Permitted Subcontractors do not engage, in any advertising or promotional activities relating to any Products that is directed primarily to customers located outside the Territory, or solicit orders from any prospective purchaser that has a principal place of business outside the Territory or that Distributor or any of its Permitted Subcontractors has reason to believe intends to distribute Products outside the Territory. If Distributor or any of its Permitted Subcontractors receives any order for Products from such a prospective purchaser, then Distributor shall, and shall cause its applicable Permitted Subcontractor to, promptly, but in any event within thirty (30) days of receipt, refer such prospective customer and order to Company. Distributor shall not, and shall ensure that its Permitted Subcontractors do not, accept any such orders. Except as otherwise provided herein, Distributor shall not, and shall ensure that its Permitted Subcontractors do not, deliver or tender (or cause or knowingly permit to be delivered or tendered) any Products for use outside the Territory. Subject to the foregoing obligations, Distributor shall be permitted to act as a distributor for third party manufacturers and service providers, *provided* that Distributor shall not be permitted to act as a distributor or otherwise represent any third party that is a Direct Competitor of Company.

2.3 Additional Obligations of Distributor. Distributor shall cause its customers to comply with all applicable terms and conditions in this Agreement and Distributor shall remain responsible for the acts and omissions of its customers with respect to the same. In the event of breach by any of Distributor's customers of the same, Distributor shall use reasonable efforts to ensure such breach is cured.

2.4 Additional Covenants of Distributor. Distributor shall not, and shall ensure that its Permitted Subcontractors do not:

2.4.1 make any additions, modifications or alterations to the Products or otherwise change the characteristics of the Products in any way, in each case, without Company's prior written consent, which Company may withhold in its sole and absolute discretion;

2.4.2 attempt to or actually copy, reverse engineer, or decompile the Products or any materials provided to Distributor by Company;

2.4.3 tamper with any Product in any manner that would reasonably be expected to cause a material alteration or change from the condition in which such Product was delivered to Distributor; and

2.4.4 without Company's prior written consent, make any promises or guarantees with reference to the Products beyond those contained in the materials and information supplied by Company or otherwise incur any liability on behalf of Company.

## 3. MANUFACTURE AND SUPPLY OF THE PRODUCTS

3.1 Supply Obligations. During the Term, Company shall use commercially reasonable efforts to manufacture and supply (or have manufactured and supplied) the quantities of Products ordered by Distributor that are set forth in the Forecasts and Purchase Orders, in accordance with the Clauses 3.4 and 3.5 herein, in accordance with mutually agreed-upon specifications as set forth in the QA Requirements Document. Company shall not be obligated to manufacture or supply any Products that are not ordered in accordance with Clauses 3.4 and 3.5 herein.

3.2 Manufacturing Standards; Quality Assurance; Registration. During the Term, Company shall, whether directly or indirectly through a third party, manufacture, store and supply all Products in accordance with Applicable Laws, including, for clarity, GMP and QSR requirements. Company shall undertake, and shall cause its Affiliates and applicable third party contractors (*e.g.*, suppliers) to undertake, all quality control and testing programs consistent with the specifications for the Products as set forth in the QA Requirements Document and in accordance with all Applicable Laws. Company shall be responsible for, at its own cost, all testing, quality control and quality assurance matters related to the manufacture of the Products and shall provide a written certificate of compliance with each batch of Product delivered to Distributor. Company shall be the initial importer and be responsible for maintaining an agent of record that maintains a complaint-handling procedure in compliance with Company's quality management system (reasonably consistently applied) and ensuring compliance across all other applicable FD&C Act requirements, as well as any other Applicable Laws. Company shall be responsible for establishment registration, establishing and maintaining medical device listing and Global Unique Device Identification Database (GUDID) database, in each case, in the Territory. Complaint handling, including MDRs, shall be handled in accordance with the QA Requirements Document.

3.3 Records and Inspections. Company shall maintain quality control documentation in sufficient detail to allow Distributor to confirm Company's compliance with its manufacturing and quality control obligations under Clause 3.2 and under the QA Requirements Document. Company shall maintain such records for each batch of Products for a period of three (3) years after Company delivers such batch of Products to Distributor. Distributor shall have the right to inspect and audit such documentation during such three (3) year period, but (a) not more than once per calendar year, and (b) not more than once with respect to a given record or set of records; unless, in each case of (a) and (b), a previous inspection revealed Company's non-compliance with its manufacturing and quality control obligations under Clause 3.2. All information obtained by Distributor will be Confidential Information of Company. All such inspections and audits shall be conducted in a manner designed to minimize the impact on Company's business.

3.4 Forecasts; Inventory. Distributor shall submit to Company a written rolling forecast (each, a "**Forecast**") of its anticipated requirements for the Products during the next succeeding twelve (12) month period. The first three (3) months

of the Forecast shall be binding and the remaining nine (9) months shall be non-binding. The first Forecast shall be submitted on the date that is three (3) months after the Commercial Activities Effective Date, and each subsequent Forecast shall be submitted within ten (10) days after the beginning of each Quarter, beginning with the next full Quarter after delivery of the first Forecast. Distributor is solely responsible for maintaining a sufficient inventory of Products.

3.5 Purchase Orders.

3.5.1 Generally. Unless the Parties otherwise agree, Distributor shall place no more than two (2) firm orders per month for the amounts set forth in the binding portion of the Forecast (each, a "**Purchase Order**"). Each Purchase Order shall set forth, at a minimum, (a) the name, part number, and quantity of each Product ordered; (b) the unit price of each Product ordered and the total purchase price; (c) the requested delivery date(s) and the location for delivery; (d) the billing and shipping address(es); and (e) any special instructions or other pertinent requirements.

3.5.2 Submission; Acceptance or Rejection of Purchase Orders. Distributor shall submit each Purchase Order at least fifteen (15) days before the requested shipping date ("**Lead Time**") from Company's or an Affiliate of Company's designated facility. Each Purchase Order shall include a requested delivery date consistent with the applicable Forecast and the Lead Time. Company may accept or reject each Purchase Order by providing Distributor written notice thereof within five (5) business days from Company's receipt of a Purchase Order. If, within such time period, Company does not provide such notice of acceptance or rejection to Distributor, then the applicable Purchase Order shall be deemed to have been accepted by Company. Company shall only be obligated to accept Purchase Orders placed in accordance with the applicable Forecast and this Clause 3.5. Notwithstanding the foregoing, Company shall not reject any portion of a Purchase Order that does not exceed one hundred twenty percent (120%) of the forecasted quantity in the applicable Forecast. Company shall provide Distributor with an expected delivery date for the relevant quantity of Product set forth in each accepted Purchase Order. Subject to the terms and conditions of this Agreement, Company will use commercially reasonable efforts to meet the delivery dates set forth in all Purchase Orders accepted by it. Notwithstanding the foregoing, Company shall not be responsible for any liability, loss or damage of any kind sustained or incurred by Distributor by reason of any delay in Company supplying the Products, except, in each case of the foregoing, to the extent that such liability, loss or damage is attributable to Company's gross negligence, intentional misconduct or material breach of this Agreement. Notwithstanding the foregoing, Company shall not be required to deliver any Product if Distributor is in default in relation to any undisputed payment obligations under this Agreement, and Company may suspend all deliveries of Product until such time as Distributor has paid in full all undisputed amounts due. For the avoidance of doubt, payment obligations that are in good faith dispute by Distributor shall not be considered as being in default for the purposes of this Clause 3.5 until such dispute has been resolved.

3.6 Shelf Life. The Product will have a minimum remaining shelf life of (a) at least three (3) years after the date of delivery pursuant to Clause 3.8, or (b) a different

shelf life specifically approved by the Distributor, in each case of (a) or (b), unless the Product has a shorter approved shelf life, in which case, the shelf life will be such Product's approved shelf life.

3.7 Demo Versions. Distributor shall be required to purchase from Company, and provide its sales force with, sufficient demonstration versions of the Products and any related ancillaries, in quantities and form as reasonably determined by the Parties.

3.8 Shipping and Delivery. Subject to Clause 3.9, Company or its Affiliates shall deliver the Product to Distributor EXW (Company's or Company's Affiliate's designated facility(ies) (Incoterms 2020)) by the delivery date specified in the relevant Purchase Order. All standard transport and insurance costs, including from Distributor's facility(ies) to local distribution hubs and/or end customers, will be borne by Distributor. Distributor shall be required to sufficiently insure all shipments of the Product with an internationally renowned insurance carrier. Company shall be responsible for the importation of the Products into the Territory, including all customs and regulatory responsibilities, and shall use commercially reasonable efforts to resolve any and all issues relative to such Product import. Company shall be responsible for the full cost of expediting shipments if there is a delay of more than ten (10) days between receipt of the Purchase Order and shipment of the Products specified in the Purchase Order (unless the delivery date set forth in such Purchase Order exceeds such ten (10) day period). For the avoidance of doubt, Company shall remain the importer of record for all Products.

3.9 Third Party Logistics Provider. Distributor shall have the right to designate and engage a third party logistics provider in connection with the shipment and delivery of the Products from the Company to the Distributor pursuant to Clause 3.8, *provided* that Distributor retains responsibility for the acts and omissions of such third party logistics provider in relation to the Products as if they were the acts and omissions of Distributor itself. To the extent Company bears any expenses in relation to any third party logistics provider engaged by Distributor, Distributor shall reimburse Company for any such expenses except as set forth in Clause 3.8.

3.10 Product Storage and Handling. Distributor shall, and shall ensure that its Permitted Subcontractors shall, store all stocks of the Products in compliance with (a) the terms of this Agreement, (b) the QA Requirements Document, (c) all Applicable Law, and (d) other reasonable instructions of the Company regarding storage of the Products that are provided to Distributor in writing from time to time (provided that such instructions to not violate or conflict with the QA Requirements Document or Applicable Law).

3.11 Acceptance and Rejection of Products.

3.11.1 All Products supplied by Company shall be examined and checked immediately, by conducting a visual inspection of external packaging, upon receipt by Distributor to ascertain that the Product's external packaging complies with the Product Specifications that can be determined based on such visual inspection (each of such defect, a "**Patent Defect**"). For the avoidance of doubt, any Shortfalls described in Clause 3.13 shall not be deemed a Patent Defect. Unless Company is, by written notice within ten (10) business days after Distributor's receipt of

the applicable Product, informed of any Patent Defect, Company shall have no liability whatsoever with respect to such Patent Defect.

3.11.2 If any Product has a Latent Defect (as defined below in this Clause 3.11.2), Distributor shall notify Company of the Latent Defect within ten (10) business days following its discovery, but in no event later than nine (9) months after Distributor's receipt of the applicable Product. "**Latent Defect**" means any (a) defect that is not attributable to the transportation or handling of the Product after delivery that is already present at the date of delivery other than a Patent Defect or (b) breach of Company's representations and warranties under Clause 10.1.1 in each case of (a) or (b), that is not discovered by Distributor despite diligent, industry standard visual inspection upon Distributor's receipt of the delivery pursuant to Clause 3.11.1. If written notice of a Latent Defect is not received by Company within such ten (10)-business day period following Distributor's discovery of such Latent Defect, the shipment shall be deemed to have been completely and correctly fulfilled, and all claims by Distributor shall be deemed waived and released.

3.11.3 All notices of Products containing a Patent Defect or a Latent Defect (each of such Product, a "**Defective Product**") delivered by Distributor to Company under Clause 3.11.1 or Clause 3.11.2 shall be accompanied by a sample of the allegedly Defective Product sufficient for Company to verify the Patent Defect or Latent Defect, as applicable.

3.12 Remedies for Defective Product.

3.12.1 In the case of allegedly Defective Product for which notice (together with sufficient sample) has been provided as set forth in the preceding Clause 3.11, Company shall promptly evaluate such sample to verify the alleged Patent Defect or Latent Defect and provide written notice of its determination after the evaluation to Distributor in writing. If the Parties disagree on whether the Product is a Defective Product, a sample of the allegedly Defective Product shall be delivered by either Party to an independent testing facility mutually acceptable to the Parties for evaluation. Except in the case of manifest error, the decision of the independent testing facility as to whether the Product is a Defective Product shall be final and binding on the Parties. If the independent testing facility determines that the Product is a Defective Product, Company shall pay the independent testing facility's fees. If the independent testing facility determines that the Product is not a Defective Product, Distributor shall pay the independent testing facility's fees and shall accept the allegedly nonconforming batch.

3.12.2 Distributor shall, at Company's discretion, return all Defective Products to Company or destroy such Defective Products, at Company's cost and expense. In the event that Company does not instruct Distributor of Company's preference for return or destruction of Defective Products within ten (10) days of the verification by Company (as notified to Distributor in writing) or the independent testing facility (as notified to both Parties in writing), as the case may be, Distributor shall be entitled to destroy such Defective Products and Company shall reimburse Distributor for reasonable and documented destruction costs. With respect to any Defective Product, Company shall, at Company's option, either (a) replace

such Defective Product without additional charge to Distributor or (b) refund the purchase price plus reasonable and documented shipping costs (including custom duties, taxes and landed costs) incurred by Distributor as soon as reasonably feasible.

3.13 Shortfalls. If Company fails to completely deliver the quantities of non-Defective Products set forth in the relevant Purchase Order (each such event, a "**Shortfall**") and is so notified by Distributor in writing within ten (10) business days after Distributor's receipt of the applicable Product delivery, Distributor shall, at its option, either (a) require Company to use expedited delivery methods, at Company's own cost and expense, to complete and deliver the remaining quantities of the Product in accordance with the relevant Purchase Order or (b) cancel all or any part of the relevant Purchase Order without penalty and receive refund of any payments with respect to the cancelled Products. If, over any three (3) month period during the Term, less than seventy-five percent (75%) of the Products ordered by Distributor are delivered by the specified delivery date, Company shall be deemed to be in material breach of the Agreement.

3.14 Minimum Annual Order. To maintain the Distributor's exclusive rights herein, Distributor shall commit to ordering two million three hundred eighty five thousand Dollars ($2,385,000) of Products during the first twelve (12) months following the Commercial Activities Effective Date. For each subsequent year during the Term, the Parties shall negotiate in good faith the minimum annual purchase targets (the "**Minimum Annual Order**"); *provided, however*, that Distributor hereby agrees to at least a ten percent (10%) annual increase of the Minimum Annual Order during the Term. For avoidance of doubt, Distributor is not limited from ordering more Products than the Minimum Annual Order (*provided* that Company shall only be obligated to supply quantities of Products in accordance with the terms and conditions of this Agreement).

3.15 Supply Failure. If, during the Term, Company suffers from a supply failure across Products at Company (whether or not such supply failure is subject to Clause 12), Company shall allocate the Products between (i) the Products to be Commercialized by Distributor in the Field in the Territory and (ii) all other Products to be Commercialized by or on behalf of Company outside of the Field in the Territory or outside of the Territory on a pro-rata basis, based on the sales of the Products in the Field in the Territory and the sale of the Products outside of the Field in the Territory or outside of the Territory in the immediate preceding calendar year.

## 4. PRICE AND PAYMENT

4.1 Upfront Payment. In consideration for Company's provision of Commercial Support to Distributor hereunder, Distributor shall pay Company a one-time, non-refundable upfront payment of four million five hundred thousand Dollars ($4,500,000) ("**Upfront Payment**"). Distributor shall pay such Upfront Payment in three (3) installments: (a) first installment of two million Dollars ($2,000,000) on or before the later of (i) ninety (90) days after the Effective Date or (ii) thirty (30) days after the Commercial Activities Effective Date; (b) a second installment of one million two hundred fifty thousand Dollars ($1,250,000), on or before the one (1)-year anniversary of the Commercial Activities Effective Date; and (c) a third installment of one million two hundred fifty thousand Dollars ($1,250,000), on or before the two (2)-year anniversary of the Commercial Activities Effective Date. For the avoidance of doubt, Distributor's payment of the Upfront Payment

shall be excluded from the calculation of Fully Loaded COGS and will be solely for sales and marketing purposes.

4.2 Initial Purchase Price. [*]

4.3 Purchase Price; List Price. [*]

[*]. For the avoidance of doubt, subject to Distributor's obligation to, at all times during the Term, comply with all Applicable Laws, Distributor shall be free to determine the price at which it resells the Products to its customers.

4.4 Failure to Achieve Minimum Annual Order. In the event that Distributor fails to achieve its Minimum Annual Order commitment in any given year during the Term, and to the extent that such failure is not the result of an action or inaction by Company or is not otherwise subject to Clause 12, (a) Company shall have the right to adjust the Purchase Price described above in its sole discretion or (b) Company shall have the right, in its sole discretion, to terminate the exclusive right to Commercialize the Products in the Field in the Territory granted to Distributor hereunder.

4.5 Payment. Company shall invoice Distributor in Dollars for all Products supplied at the then-current Purchase Price (calculated as the number of units supplied in that shipment multiplied by the then-current Purchase Price). Distributor shall pay all amounts due and invoiced for each delivery of Product within thirty (30) days after the date on which Distributor receives the invoice. Payment of each invoice shall occur in Dollars by wire transfer in immediately available funds to Company's bank account to be provided by Company to Distributor, referencing this Agreement and identifying the specific invoice that the payment satisfies. At the Commercial Activities Effective Date, and on each anniversary of the Commercial Activities Effective Date during the Term, the Purchase Price will be established in Dollars. [*]

4.6 Records. Distributor, its Affiliates, and Permitted Subcontractors, shall keep complete and accurate records pertaining to the use, sale and other disposition of the Product, including for each lot number of Product, the quantity shipped and where the lot was shipped. Distributor shall, and shall ensure that its Affiliates and Permitted Subcontractors shall, keep its or their respective records for at least three (3) years from the termination or expiration of this Agreement or for such longer

period if and as required by Applicable Law. Distributor shall, and shall ensure that its Affiliates and Permitted Subcontractors shall, make available such records to Company as required for compliance with Applicable Laws as Company may reasonably request in writing. Notwithstanding the foregoing, Distributor further agrees to make written reports available to Company relating to the sale of the Product on a Quarterly basis, with each report setting forth the number of Product sold during the immediately prior Quarter by customer in the Territory in which the Product was sold. Such reports shall be provided to Company no later than forty-five (45) days following the end of the corresponding Quarter.

4.7 Audit Rights. Company shall have the right to visit Distributor's corporate offices and facilities where the Product is stored or shipped to its customers from time to time during the Term to perform a quality audit of Distributor's records concerning storage, distribution (including shipping and handling), sales and accounting of the Product. Such visits shall be conducted during normal business hours upon at least five (5) business days' prior written notice, provided that such quality audit pursuant to this Clause 4.7 (a) shall not be conducted more than once per calendar year, and (b) shall not be conducted more than once with respect to a given record or set of records, unless, in each case of (a) and (b), a previous audit revealed Distributor's non-compliance with this Agreement. All information obtained by Company during such audit will be Confidential Information of Distributor. All audits pursuant to this Clause 4.7 shall be conducted in a manner designed to minimize the impact on Distributor's business.

4.8 Taxes. All prices for the Product are exclusive of any applicable value added or any other sales tax, for which Distributor shall be additionally liable, if applicable. Notwithstanding anything herein to the contrary, taxes in the Territory now or hereafter imposed with respect to the transactions contemplated hereunder (with the exception of income taxes or other taxes imposed upon Company and measured by the gross or net income of Company) shall be the responsibility of Distributor, and if paid or required to be paid by Company, the amount thereof shall be added to and become a part of the amounts payable by Distributor hereunder. All payments due by a Party under this Agreement shall be made without any deduction or withholding for taxes ("**Tax Deductions**") unless a Tax Deduction is required by Applicable Law. A Party shall promptly, upon becoming aware that a Tax Deduction must be made (or that there is any change in the rate or the basis of a Tax Deduction), notify the other Party accordingly. If a Party is required to make a Tax Deduction, such Party shall make that Tax Deduction, within the time allowed and in the minimum amount required by Applicable Law or, if lower, by the amount provided for by the applicable tax treaty for the avoidance of double taxation. As soon as reasonably practicable but within sixty (60) days of making a Tax Deduction, the Party shall deliver to the other Party evidence reasonably satisfactory to such other Party that the amount corresponding to the Tax Deduction has been paid to the relevant taxing authority, according to the relevant procedure, together with such other documentation as such other Party may reasonably require to ensure the Tax Deduction is recognized as tax credit under the applicable income tax law and together with such other documentation as such other Party may reasonably require for making submissions to any revenue or other authority. Such other Party shall co-operate in completing any procedural formalities necessary for the other to obtain authorization to make the payment without Tax Deduction or in the minimum amount provided for by the applicable tax treaty for the avoidance of double taxation.

4.9 Late Payments. Any undisputed payment not made by Distributor on or before the date such payment becomes due under this Agreement shall bear interest at a floating rate equal to the prime interest rate quoted by *The Wall Street Journal*, Internet U.S. Edition at www.wsj.com on the date when the undisputed payment was due, and as it may be adjusted from time to time thereafter, plus three percent (3%) or the highest rate permitted by Applicable Laws (whichever is lower), computed from the date such undisputed payment was due until the date Distributor makes such payment. If such prime interest rate is no longer quoted, the Parties shall agree on a reasonable substitute therefor. The payment of such interest shall not limit Company from exercising any other rights it may have as a consequence of the lateness of any undisputed payment.

## 5. REGULATORY

5.1 Compliance. Each Party shall comply in all material respects with all Applicable Laws that relate to the performance of such Party's obligations under this Agreement. Distributor shall comply with, and shall ensure its Permitted Subcontractors comply with, all Applicable Laws, including but not limited to the relevant laws, rules or regulations concerning the Commercialization of the Product in the Territory. During the Term, each Party shall use reasonable efforts to inform the other Party of any new laws, rules or regulations in the Territory (or any part of it) or any amendments, to the current laws, rules or regulations that may have any impact on Commercialization of the Products in the Territory.

5.2 Regulatory Audit or Inspection of Company; Adverse Event Reporting. Each Party shall advise the other Party of any compliance issues or queries, including adverse event reporting, or contact and complaints made by any Regulatory Authorities, including but not limited to any quality assurance problems raised by the FDA with Company's manufacturing facilities used in the manufacture of the Products. Company shall inform Distributor by providing reasonable advance written notice of any regulatory audit or inspection of Company's facilities relating to the manufacture of the Products. Distributor shall have the right but not obligation to review and comment upon any correspondence by Company to the Regulatory Authority generated as a result of such audit or inspection prior to submission of such correspondence by Company to the Regulatory Authority, and Company shall consider Distributor's comments in good faith. Company, at its sole cost, shall take all steps it reasonably deems necessary to correct deficiencies, if any, found through the adverse event reporting or an audit or inspection by the Regulatory Authorities relating to the manufacture or storage of the Products. Company shall notify Distributor reasonably promptly in writing in the event any material action is taken or threatened by a Regulatory Authority relating to the manufacture or storage of any Product, or relating to the Company's facility in which such manufacture or storage occurs, or which may impair the ability of Company to supply the Products in accordance with this Agreement.

5.3 Responsibility for Marketing Authorizations. Company shall be responsible for applying for, obtaining and maintaining all Marketing Authorizations for the Product(s) in the Field in the Territory, in Company's name. Company shall be responsible for all communications with applicable Regulatory Authorities in the Territory. Distributor will, upon Company's request and at Company's expense (a) provide reasonable regulatory support to assist Company in meeting the requirements of the Regulatory Authority in the Territory and (b) reasonably cooperate with Company with respect to the Marketing Authorization process of

the Product with the applicable Regulatory Authorities and/or to any updates, modifications, amendments and/or renewals thereof.

5.4 Regulatory Documentation. Promptly after the Effective Date, Company shall provide to Distributor all applicable and publicly available regulatory information relating to the manufacture and supply of the Products (including, for clarity, the Marketing Authorizations and all documentation and data with respect thereto) in the Field in Territory as reasonably requested by Distributor. If Company makes any changes to a Product that requires Marketing Authorizations, Company shall provide (a) a prior written notice thereof to Distributor and (b) all relevant regulatory documentation and data with respect thereto.

5.5 Product Improvements; New Products. Company shall be solely responsible, in its sole discretion and at its sole cost, for seeking Marketing Authorizations for any improvements to the Products, including any new Products, and expanded indications for any Product in the Territory. Distributor may provide input to Company on the relative importance of Product changes and improvements, new Products, and labeling changes in the Territory. Company shall reasonably consider such input with respect to seeking such Marketing Authorizations, but all decisions regarding the foregoing shall be at the sole discretion of Company.

5.6 Distributor Obligations. Distributor shall be responsible for seeking, obtaining and maintaining all authorizations, licenses, registrations and permits required to be obtained by Distributor to enable Distributor to act as distributor of the Product pursuant to this Agreement; *provided* that, upon Distributor's reasonable request and at Distributor's expense, Company shall provide (a) all documentation that is reasonably necessary for Distributor to fulfill the foregoing obligations and (b) reasonable assistance and cooperation in connection therewith.

5.7 Additional Obligations. Additional obligations of each Party with respect to Marketing Authorizations and regulatory activities are set forth in the QA Requirements Document.

5.8 Regulatory Audits and Inspections of Distributor.

5.8.1 Upon reasonable notification (but not less than thirty (30) days), Company shall be entitled to conduct an audit of regulatory systems, procedures and practices of Distributor and its Permitted Subcontractors, including on-site evaluations and solely to the extent that such audits specifically relate to the Products.

5.8.2 With respect to any inspection of Distributor or its Permitted Subcontractors by any Regulatory Authority relating to the Products, Distributor shall notify Company of such inspection (a) no later than two (2) business days after Distributor or its applicable Permitted Subcontractor receives notice of such inspection or (b) within two (2) business days after the completion of any such inspection of which Distributor or its applicable Permitted Subcontractor did not receive prior notice thereof Distributor shall promptly provide Company with all information in Distributor's Control specifically related to any such inspection by the Regulatory Authority. To the extent required under Applicable Law, Distributor shall permit Regulatory Authorities worldwide to conduct inspections of Distributor specifically relating to the Products and shall ensure that all its Affiliates and Permitted

Subcontractors permit such inspections specifically relating to the Products. Company shall have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority), to be present at any such inspection at its sole cost and expense. Following any such regulatory inspection related to the Product, Distributor shall provide Company with an unredacted copy of any finding, notice, or report provided by any Regulatory Authority related to such inspection (to the extent specifically related to the Product) within two (2) business days of Distributor or its applicable Permitted Subcontractor receiving the same.

5.9 Regulatory Action. Distributor shall immediately notify Company of any information it receives regarding any threatened or pending action, inspection or communication by any Regulatory Authority, which would reasonably be expected to affect the safety or efficacy claims of any Product, the continued Commercialization of the Product in the Territory, or the exploitation of the Product elsewhere in the world. Without limiting the foregoing, unless the Parties otherwise agree: (a) Distributor shall not communicate with any Regulatory Authority having jurisdiction in or outside the Territory, unless so ordered by such Regulatory Authority or required by Applicable Law, in which case Distributor shall immediately notify Company of such order; and (b) Distributor shall not submit any regulatory filings or seek Marketing Authorizations for the Product in or outside the Territory.

5.10 Recalls.

5.10.1 Future Recalls. Promptly after being notified of a Recall, Company shall oversee all Recalls within the Territory and Distributor shall assist with such Recall in accordance with the QA Requirements Document. Company shall promptly work to resolve any Recalls on a Product-by-Product basis and shall notify Distributor in writing as soon as practicable following such resolution. All costs and expenses in connection with a Recall in the Territory incurred by Distributor shall be borne by Company (or reimbursed by Company, as applicable), including (a) the costs related to the dissemination of relevant information to customers, (b) the costs associated with the collection and shipment from customers to Distributor of the recalled Products sold by Distributor and (c) the costs of replacing such Products, including the cost of shipping the replacement Products to the affected customers; except, in each case of (a) through (c), to the extent such Recall is attributable to Distributor's negligence, intentional misconduct or breach of this Agreement.

5.10.2 Existing Recall. To the extent a Recall exists as of the Effective Date ("**Existing Recall**"), Company shall use diligent efforts to fully resolve the Existing Recall prior to the Commercial Activities Effective Date, provided that failure by FDA to provide Company a notice of full resolution of the Existing Recall prior to the Commercial Activities Effective Date shall not be deemed a breach of Company's obligations to use diligent efforts in accordance with this Clause 5.10.2, nor a material breach of this Agreement, in each case, so long as such failure is not directly attributable to a related act or omission by the Company. Company shall notify Distributor in writing immediately following full resolution of an Existing Recall.

## 6. COMMERCIALIZATION OF THE PRODUCTS

6.1 Commercial Activities Effective Date. Parties shall use commercially reasonable efforts to commence Commercialization as soon as possible after the Effective Date, but in any event no later than October 1, 2022 ("**Commercial Activities Effective Date**"). Commencing on the Commercial Activities Effective Date, and throughout the Term, Distributor shall conduct all Commercialization for the Products in the Field in the Territory at its own cost and expense. Distributor will exercise reasonable efforts, but in any event no less than industry standards, Commercialize the Products in the Field in the Territory. Distributor shall dedicate an appropriate number of sales and support personnel to achieve the Minimum Order threshold, and shall employ an appropriate sales force structure to promote the Products effectively. In the pre-Marketing Authorization phase, subject to Applicable Laws, Distributor will use reasonable efforts in an unapproved product environment, to communicate with the customers on disease awareness, medical education and information, product availability and pricing.

6.2 Product Information; Promotional and Marketing Materials.

6.2.1 Company Promotional Materials and Product Information. Company shall: (a) provide Distributor: (i) Company's current supply of applicable (and compliant with all Applicable Law) promotional materials used by Company to promote the Products in the Field in the Territory, as well as (ii) using reasonable efforts, but in any event no less than industry standards, information on research and clinical references, and grant Distributor authority to utilize such materials and references as appropriate; (b) provide, using reasonable efforts, but in any event no less than industry standards, Distributor's sales force with technical training with respect to the Products as is reasonably requested by Distributor; and (c) promptly forward to Distributor any sales inquiries relating to the Products within the Territory. For the avoidance of doubt, Distributor shall pay for all costs associated with printing, importing and shipping of such promotional materials. Distributor may request additional promotional materials or content with respect to the Products. Company shall review and, if such request is reasonably appropriate, approve the request, and/or create or develop such additional promotional materials or content for Distributor; *provided* that Distributor shall pay for all costs associated with developing, procuring and shipping of such additional promotional materials.

6.2.2 Distributor Promotional Materials. Any promotional materials or content developed or created solely by Distributor ("**Distributor Promotional Materials**") shall remain the property of Distributor, *provided* that Distributor shall furnish a copy of all Distributor Promotional Materials to Company for review to ensure, among other things, accuracy and compliance with Applicable Law. Distributor shall not use or publicly disclose any Distributor Promotional Materials without the prior written approval of Company, which approval shall not be unreasonably withheld. Distributor hereby grants to Company a non-exclusive, royalty-free, fully paid-up right and license to use, display, reproduce, distribute, perform and create derivative works of any Distributor Promotional Materials for the purpose of Commercializing the Products outside of the Territory.

6.3 Commercialization Plan. Distributor shall generate an annual written report detailing the commercial strategy, sales tactics and marketing tactics for current Products that Distributor shall implement in the Field within the Territory

("**Commercialization Plan**"). Distributor shall provide Company with a copy of the Commercialization Plan at least sixty (60) days prior to each anniversary of the Commercial Activities Effective Date. Company shall have the right to review and comment on the Commercialization Plan and Distributor shall consider in good faith all of Company's comments timely received by Distributor. The Parties shall discuss, and mutually agree upon, the Commercialization strategy and tactics for any new Products in the Field in the Territory, and the Parties shall update the Commercialization Plan accordingly, provided that final determination of the Commercialization strategy and tactics implemented for the existing Products (*i.e.*, Products that are on the Product List as of the Effective Date) in the Field in the Territory shall be determined by Distributor. Distributor shall carry out Commercialization of the Products (whether existing or new) in the Territory in accordance with the Commercialization Plan and this Agreement.

6.4 Commercial Support Requirements. Company agrees to provide and maintain commercial support at a level mutually agreed-upon by Company and Distributor materially as set forth in Schedule 6.4 attached hereto ("**Commercial Support Requirements**"). The Commercial Support Requirements, including an annual plan for support for commercial programs, market development activities and Commercial Support, in each case, in the Field in the Territory, shall be reviewed and approved by both Parties annually. Company shall provide, throughout the Term of the Agreement, at a minimum, the [*] based in the Territory for market development activities that include SEEG courses conducted in the Territory. Company shall have the right, in its sole discretion to alter commercial team members supporting Distributor at any time during the Term; *provided, however*, that in the event that a change in the Company's commercial team causes the level of commercial support to materially differ from the agreed upon Commercial Support Requirements and, because of such change, Distributor incurs additional costs in performing its obligations under this Agreement, then Company will reimburse such reasonable, documented costs incurred by Distributor, up to an amount not to exceed five hundred thousand Dollars ($500,000).

## 7. SERVICE LEVELS

7.1 Distributor Obligations. Distributor shall perform, and shall ensure its Permitted Subcontractors perform, its or their activities under this Agreement with requisite care, skill and diligence, and using individuals with proper skill, training and experience to carry out such activities to the agreed standards. Distributor shall, and shall ensure its Permitted Subcontractors, comply with all applicable Company policies and procedures that Company has provided to Distributor and limited to as they relate to Commercialization of the Products in the Field in the Territory.

7.2 Support Levels. [*]

## 8. INTELLECTUAL PROPERTY; LICENSE

8.1 Existing IP. Each Party will retain all right, title and interest in, to and under all intellectual property it Controls prior to the Effective Date or that it develops or acquires independently during the Term without referencing or incorporating the Confidential Information of the other Party. For the avoidance of doubt, Company shall retain all right, title and interest in and to all Company IP.

8.2 License. Subject to the terms and conditions of this Agreement, Company hereby grants to Distributor, during the Term, an exclusive, non-transferrable (except as provided in Clause 16.1), non-sublicensable (except to Permitted Subcontractors in accordance with Clause 2.1.1), royalty-free and fully paid-up license, under (a) the

Company IP, solely to the extent necessary to Commercialize the Product in the Field in the Territory.

8.3 Additional Trademark Obligations. Company reserves the right to modify its trademarks and trade names related to the Product ("**Marks**") or substitute alternative marks for any or all of the Marks at any time. Distributor agrees to use the Marks in connection with the Product as may be designated in writing in advance by Company. For clarity, Company IP includes all Marks. Distributor shall not remove, modify, or obscure Marks affixed to the Product without the prior written consent of Company. Except as set forth in Clause 8.2 or this Clause 8.3, nothing contained in this Agreement shall grant to Distributor any right, title or interest in or to the Marks whether or not specifically recognized or perfected under Applicable Laws. At no time during or after the expiration of the Term, shall Distributor challenge or assist others to challenge Marks or the registration thereof or attempt to register any trademarks, marks or trade names confusingly similar to Marks. Distributor shall have the right to indicate in its advertising and promotion materials and on its stationery that it is an "**authorized distributor**" of the Product in the Territory.

8.4 No Implied License. Except for the license expressly granted in Clause 8.2 of this Agreement and other rights expressly set forth in this Agreement, (a) Company retains all rights in, to or under the Company IP and (b) neither Party grants to the other Party any right or license to any intellectual property rights of such Party.

8.5 Product IP. Distributor acknowledges and agrees, and shall cause its Permitted Subcontractors to acknowledge and agree, that, as between the Parties, all intellectual property (a) arising out of the Products, or this Agreement or use of any Confidential Information provided by Company or its Affiliates under this Agreement, including the Company IP, and (b) any additions, alterations or improvements developed by Distributor or any of its Permitted Subcontractors that arise out of and are directly related to any of the foregoing described in subclause (a) (individually and collectively, the "**Product IP**"), shall be the exclusive property of Company. For clarity, Company IP includes all Product IP. Further, Distributor agrees, and shall cause its Affiliates and Permitted Subcontractors to agree, that if it or any of them provides Company with any suggestions, comments, disclosures or other feedback about any Products or Company IP (the "**Feedback**"), (i) any modifications made by Company based on or related to the Feedback shall be owned exclusively by Company and (ii) Company shall have exclusive rights and interests on any product, service or intellectual property incorporating such Feedback ((i) and (ii) collectively, the "**Feedback-Related IP**"). Distributor hereby irrevocably assigns, and shall cause each of its Permitted Subcontractors to assign, to Company all of its and their respective right, title and interest in, to and under any Product IP, Feedback, or Feedback-Related IP, as well as -related modifications and any goodwill associated with any of the foregoing.

8.6 Execution of Additional Documents. Each Party shall, and shall cause its Affiliates, and all independent contractors, employees and agents of such Party, to cooperate with the other Party and take all reasonable actions and execute such agreements, declarations, assignments, legal instruments and documents as may be reasonably required to perfect the other Party's right, title and interest in and to all intellectual property rights as set forth in this Clause 8, in each case of the foregoing, upon such other Party's request and at such other Party's expense.

9. **CONFIDENTIALITY**

9.1 Obligation of Confidentiality. Except as provided in Clause 9.2, the Parties shall at all times during the Term and for five (5) years after its expiration or termination (except in the case of trade secrets, in which the confidentiality obligations hereunder shall survive for so long as such Confidential Information remains a trade secret under Applicable Law):

9.1.1 keep all Confidential Information of the other Party confidential and accordingly shall not disclose any such Confidential Information to any third party;

9.1.2 not use any Confidential Information of the other Party for any purpose other than to exercise its rights or to perform the obligations under this Agreement; and

9.1.3 procure that any Person to whom any Confidential Information is disclosed by it complies with the restrictions contained in this Clause 9.

9.2 Permitted Disclosures; Exceptions. Any Confidential Information may be disclosed by the receiving Party:

9.2.1 if Distributor is the receiving Party, subject to Company's prior written consent on a case-by-case basis, to any customers or prospective customers, to the extent that such Confidential Information is materially relevant, from a scientific or promotional perspective, for said customer or prospective customer;

9.2.2 to any of its employees, consultants or other agents, or potential bankers, investors (or potential investors), acquirors (or potential acquirors), attorneys, accountants, financial advisors and/or insurers, in each case, on a need-to-know basis, *provided* that such disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Clause 9 and subject, in each case, to the receiving Party using its best endeavors to ensure that the receiving party keeps the same confidential and does not use the same except for the purposes for which the disclosure is made;

9.2.3 due to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law; provided that the receiving Party shall first have given notice, to the extent legally permitted, to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided further* that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to the information that is legally required to be disclosed in response to such court or governmental order and that the confidentiality and non-use obligations of the Party disclosing

such Confidential Information in response to such court or governmental order shall otherwise remain in full force and effect;

9.2.4 if and to the extent the information (a) is public knowledge or already known (as evidenced by written and dated documentation) to the receiving Party at the time of disclosure, (b) subsequently becomes public knowledge, after disclosure by the disclosing Party, other than by breach of this Agreement, (c) is obtained by the receiving Party from a third party which is itself not subject to obligations of confidentiality or (d) is independently developed by the receiving Party without the use of the disclosing Party's Confidential Information. For clarity, any such information shall not be considered "Confidential Information"; and

9.2.5 if and to the extent that the disclosing Party has given prior written consent to the disclosure, on a case-by-case basis.

9.3 Return or Destruction of Confidential Information. Upon the written request of the disclosing Party, or promptly after the expiration or termination of the Term, the receiving Party shall, at the disclosing Party's discretion, promptly destroy or return to the disclosing Party all documentary, electronic or other tangible embodiments of the Confidential Information to which the receiving Party does not retain rights hereunder and any and all copies thereof, and destroy those portions of any documents that incorporate or are derived from the Confidential Information to which the receiving Party does not retain rights hereunder, except that the receiving Party may retain one copy thereof, to the extent that the receiving Party requires such Confidential Information for the purpose of performing any obligations or exercising any rights under this Agreement that may survive such expiration or termination, or for archival purposes.

9.4 Ownership of Confidential Information. Except as provided in this Agreement, all Confidential Information (and all intellectual property therein) of the disclosing Party under the Agreement is and shall remain the disclosing Party's property.

9.5 Publicity. Company may list and refer to Distributor (including use of Distributor's name and logo) as an authorized reseller or distributor of the Products on Company's website, proposals and presentations. During the Term of this Agreement, Distributor may indicate to the public that it is the authorized exclusive distributor of the Products in the Field within the Territory.

## 10. REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMER

10.1 Representations, Warranties and Covenants of Company. Company represents, warrants and covenants, as applicable, to Distributor that:

10.1.1 all Products supplied hereunder will (a) materially comply with the Product Specifications, (b) be free of material defects in function, workmanship or material, (c) be of merchantable quality and fit and suitable for Commercialization, (d) be free and clear of any and all encumbrances, liens or other third party rights or claims, and (e) be manufactured in material compliance with all Applicable Law, this Agreement and the relevant QA Requirements Document;

10.1.2 to Company's knowledge, the Products supplied hereunder do not infringe, misappropriate or otherwise violate any intellectual property rights of a third party;

10.1.3 all issued patents within the Company IP have been prosecuted and maintained by Company in good faith and are in full force and effect, and, to Company's knowledge, all pending patent applications within the Company IP are being prosecuted and maintained in good faith and in accordance with all Applicable Law;

10.1.4 Company has not received any written notice of a claim or written threat of a claim or litigation made by any Person against Company or its Affiliates that alleges that any Company IP existing as of the Effective Date and licensed to Distributor hereunder is invalid or unenforceable (other than patent office actions or the actions of any Regulatory Authority);

10.1.5 Company has not received written notice from a third party claiming that a patent owned by such third party would be infringed by the Commercialization of any Product in the Field in the Territory, and no third party has threatened in writing to make any such claim;

10.1.6 the inventions claimed or covered by the Company IP licensed to Distributor hereunder (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof, (b) are not a "subject invention" as that term is described in 35 USC. §201(e), (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 USC. §§200-212, as amended, or any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401 and (d) are not the subject of any licenses, options or other rights of any governmental authority, within the Territory;

10.1.7 Company has prepared, maintained and retained all regulatory documentation and regulatory licenses for the Products (including, for clarity, all Marketing Authorizations and any regulatory documentation and supporting data related thereto) in material accordance with Applicable Law;

10.1.8 Company has conducted, and has used reasonable efforts to cause its contractors and consultants to conduct, the development and manufacture of the Products (including all clinical studies) in accordance with Applicable Law; and

10.1.9 it has the full right, power and authority to grant the licenses under this Agreement.

10.2 Representations, Warranties and Covenants of Distributor. Distributor represents, warrants and covenants, as applicable, to Company that:

10.2.1 as of the Commercial Activities Effective Date, it will be authorized, either directly, or indirectly through agents, to import (as applicable), supply and distribute and it shall hold and maintain all licenses necessary

to import (as applicable), supply and distribute the Products in the Territory;

10.2.2 Distributor currently has, and will maintain during the Term, (a) sufficient qualified and trained personnel and resources, and (b) necessary financial and technical capacity to effectively fulfill its obligations related to the Products as contemplated in this Agreement;

10.2.3 Distributor shall comply with the U.S. Foreign Corrupt Practices Act of 1977 (as modified or amended), and Distributor warrants that (a) it has not and will not directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value, to improperly seek to influence any government official, (b) it is not an employer, officer or agent of a Governmental Authority or Regulatory Authority within the Territory (or elsewhere), (c) it has never been subject to any disciplinary action relating to fraud or corruption by any Governmental Authority or Regulatory Authority within the Territory (or elsewhere), and (d) it has never been the subject of a governmental investigation or litigation involving allegations of fraud or corruption;

10.2.4 Distributor has not marketed, sold or otherwise distributed, does not market, sell, or otherwise distribute, and will not knowingly market, sell or distribute during the Term, any products that would reasonably be expected to prejudice Company's business interests or create a conflict of interest in handling Company's Confidential Information; and

10.2.5 Distributor shall, upon request, provide Company a true, complete and accurate list of all products currently represented in the Territory by it.

10.3 Representations, Warranties and Covenants of Each Party. Each Party represents, warrants and covenants, as applicable, to the other Party that:

10.3.1 it is duly incorporated and validly existing in good standing under the Applicable Laws of its jurisdiction of incorporation and has full corporate power and authority to enter into this Agreement and the QA Requirements Document and to conduct the activities allocated to it hereunder and thereunder;

10.3.2 it is duly authorized to execute and deliver this Agreement and the QA Requirements Document and to perform its obligations hereunder and thereunder. Each of the Persons executing this Agreement and the QA Requirements Document on its behalf has been duly authorized to do so by all requisite corporate action;

10.3.3 each of this Agreement and the QA Requirements Document is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement and the QA Requirements Document does not conflict with any agreement, instrument or understanding, oral or written, to which such Party or its Affiliates is a party or by which such Party or its Affiliates or its or their respective assets may be bound, nor violate any law or regulation of any Governmental Authority having jurisdiction over it;

10.3.4 as of the Effective Date, it is not and, during the Term, it will not, enter into any agreement or arrangement with any third party which in any way whatsoever conflicts or is incompatible with any term of this Agreement or any of the rights granted to such Party from the other Party (or any of the rights granted by such Party to the other Party) hereunder;

10.3.5 it will perform its obligations, and shall ensure its Affiliates and all third parties that it engages with respect to activities directed to the Products shall perform their obligations, under this Agreement and such performance shall comply with all Applicable Laws;

10.3.6 it will comply with its obligations (and shall ensure its Affiliates and all third parties that it engages with respect to activities directed to the Products shall comply with the obligations) set out in this Agreement and associated Schedules, the applicable QA Requirements Document and the Commercial Support Requirements;

10.3.7 it is aware of no action, suit or inquiry or investigation instituted by any Regulatory Authority or by any other Person that questions or threatens the validity of this Agreement or the QA Requirements Document; and

10.3.8 as of the Effective Date and at all times during the Term, neither Party, nor any of its Affiliates or other Persons engaged by it, has been or will be Debarred/Excluded, or otherwise disqualified or restricted by the FDA pursuant to 21 C.F.R. 312.70 or any other Regulatory Authority or foreign equivalent thereof ("**Disqualified**"), and during the Term, neither it, nor any of its Affiliates, shall use, in any capacity in connection with the obligations to be performed under this Agreement, any Person who has been Disqualified. Each Party acknowledges and agrees that this certification imposes a continuing obligation on it to notify the other Party promptly if this warranty is no longer accurate, and that if, during the Term of this Agreement, it becomes aware that it or any of its Affiliates or its or their respective employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to such Party or any such Person becoming a Disqualified entity or individual, such Party will promptly notify the other Party.

10.4 No Additional Company Warranties. In the event Distributor or any of its Permitted Subcontractors subjects itself to any representations, warranties and/or covenants to a customer more extensive than the obligations imposed upon Company under this Agreement, then Distributor alone shall be responsible to the customer with respect to such representations, warranties and/or covenants that are more extensive than those made by Company herein and Distributor shall have no recourse against Company with respect thereto. Distributor shall, and shall ensure that its Permitted Subcontractors shall, take any other actions, including the usage of any legally enforceable disclaimer, which may be required by Applicable Law of the Territory to prevent any creation of implied warranties by Company.

10.5 No Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DISTRIBUTION OR SALE OF THE PRODUCT. EXCEPT FOR THE

CONTRACTUAL PROVISIONS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO THE PRODUCT (OR COMMERCIALIZATION THEREOF), INCLUDING, BUT NOT LIMITED TO, ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS.

## 11. INDEMNIFICATION AND INSURANCE

11.1 By Company. Company shall defend, indemnify and hold harmless Distributor, its Affiliates and its and their respective directors, employees and agents, and their respective successors, heirs and assigns (each, a "**Distributor Indemnitee**") against all claims, demands, actions, losses, expenses, damages, liabilities, costs made by a third party (including interest, penalties and reasonable attorneys' fees) and judgements suffered by a Distributor Indemnitee (individually and collectively, "**Losses**"), to the extent they are due to and arise out of or in connection with (a) Company's breach of any of its representations, warranties or obligations under this Agreement, (b) gross negligence or wilful misconduct of any Company Indemnitee in connection with this Agreement, (c) damage to property or injury or death of persons resulting directly from a defect in Product manufactured by Company, *provided* that (i) such defect existed at the time the Product was shipped by Company, (ii) no modification to the Product was made without Company's written consent, (iii) the Product was not expired at the time of use, and (iv) the Product was used in accordance with such Product's instructions for use, or (d) any claim that alleges that any Product provided hereunder or the Commercialization thereof infringes upon, misappropriates or otherwise violates any intellectual property rights of a third party; in each case of (a) through (d), except to the extent that such Losses arise out of any matter for which Distributor has obligations to indemnify a Company Indemnitee pursuant to Clause 11.2, with respect to which each Party will indemnify the other Party in proportion to their respective liability for such Losses.

11.2 By Distributor. Distributor shall defend, indemnify and hold harmless Company and its Affiliates and its and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (each, a "**Company Indemnitee**") against all Losses to the extent arising out of or in connection with (a) the transportation, storage, use, or Commercialization of Products in the Field in the Territory by or on behalf of Distributor or its Permitted Subcontractors; (b) Distributor's breach of any of its representations, warranties or obligations under this Agreement, (c) gross negligence or wilful misconduct of any Distributor Indemnitee (which, for clarity, includes its Permitted Subcontractors) in connection with this Agreement, (d) any product liability claims relating to the Products solely to the extent that a claim is based on Distributor's or its Permitted Subcontractors' Commercialization, or other handling, promotion, storage, distribution, sale or use of the Product, (e) intellectual property infringement solely to the extent arising out of Distributor's Commercialization of any Product in combination with any other device or technology that (i) was not supplied by Company or (ii) otherwise was not authorized in writing by Company for such combination or (f) damage to property or injury or death of persons occasioned by, or in connection with, the acts or omissions of any Distributor Indemnitee, including through the use of any motor vehicle or other equipment or property in connection therewith; or (g) any claims by a customer based upon any representations, warranties and/or covenants by Distributor or its Permitted

Subcontractors to a customer which is more extensive than those representations, warranties and/or covenants made by Company under this Agreement as set forth in Clause 10.4, in each case of (a)-(g), except to the extent such Losses arise out of any matter for which Company has obligations to indemnify any Distributor Indemnitee pursuant to Clause 11.1, with respect to which each Party will indemnify the other in proportion to their respective liability for such Losses.

11.3 Procedures for Indemnification. The indemnity given by each Party pursuant to Clauses 11.1 or 11.2 shall be subject to the following conditions:

11.3.1 the Party seeking indemnification (the "**Indemnified Party**") shall promptly notify the other Party (the "**Indemnifying Party**") in writing of a description of the applicable third party claim or proceeding and the nature and amount of any Losses (an "**Indemnification Claim Notice**") in respect of which it intends to claim indemnification under this Clause 11 upon actual knowledge of any such claim or proceeding resulting in such Losses; *provided*, *however*, that any delay to notify shall not excuse any obligation of the Indemnifying Party except to the extent such delay materially prejudices the defense of such claim;

11.3.2 no admissions of liability or compromise or offer of settlement of any claim shall be made by the Indemnified Party without the prior written consent of the Indemnifying Party;

11.3.3 the Indemnifying Party shall have full control over any claim, proceedings or settlement negotiations in respect of which it is providing the indemnity, provided that the Indemnified Party shall have the right to participate in any such claim, proceedings, or settlement negotiations represented by its own counsel at its own cost and expense;

11.3.4 the Indemnified Party shall cooperate as may be reasonably requested by the Indemnifying Party (and at the Indemnifying Party's expense) in order to ensure the proper and adequate defense of any action, claim or liability covered by this indemnification; and

11.3.5 the Indemnifying Party may not settle or otherwise dispose of any claim without the prior written consent of the Indemnified Party unless such settlement includes only the payment of monetary damages (which are fully paid by the Indemnifying Party), does not impose any injunctive or equitable relief upon the Indemnified Party, does not require any admission or acknowledgment of liability or fault of the Indemnified Party and contains an unconditional release of the Indemnified Party in respect of such claim.

11.4 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR LOST PROFITS, PUNITIVE, INDIRECT, INCIDENTAL, EXEMPLARY, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF, OR IN CONNECTION WITH THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS OR ACTIVITIES UNDER THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

11.5 Exclusions from Limitations of Liability. Notwithstanding anything contained herein to the contrary, Clause 11.4 shall not apply to: (a) any damages arising out

of or relating to a Party's failure to comply with its confidentiality obligations; (b) personal injury, including death, and damage to tangible property; (c) gross negligence, willful or intentional acts or omissions of a Party or its employees or subcontractors; or (d) a breach of any of the licenses granted under this Agreement. For the avoidance of doubt, any damages awarded to a third party for which a Party is obligated to indemnify the other Party under this Agreement shall be considered direct damages not subject to any limitation on liability.

11.6 Insurance. Each Party acknowledges and agrees that during the Term, it shall maintain insurance, including products liability coverage and comprehensive general liability insurance, adequate to cover its obligations under this Agreement and which are consistent with normal business practices of prudent companies similarly situated. Without limiting the generality of the foregoing, during the Term, Distributor shall maintain, at its own expense, (a) commercial general liability insurance, to include premise and operations coverage, and related contractual liabilities in amounts no less than [*] per occurrence for personal injury, bodily injury and injury or destruction of property, and (b) products/completed operations and related contractual liabilities coverage in amounts no less than [*] per occurrence with an internationally recognized insurance carrier. Distributor will furnish to Company upon its written request, a Certificate of Insurance evidencing such coverages.

## 12. FORCE MAJEURE

12.1 Definition. "**Force Majeure**" means, in relation to either Party, a circumstance beyond the reasonable control of that Party (the "**Claiming Party**"), including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, lock-outs, strikes and other industrial disputes (except for a strike, lockout or labor disturbance with respect to the Claiming Party's or its Affiliates' respective employees or agents), fire, floods, pandemic, earthquakes or other acts of God, or any generally applicable action or inaction by any Governmental Authority (but excluding any government action or inaction that is specific to the Claiming Party or its Affiliates, such as revocation or non-renewal of the Claiming Party's or its Affiliate's license to conduct business), or omissions or delays in acting by the other Party, which prevents the Claiming Party from complying with any or all of its obligations under this Agreement.

12.2 Delays and Non-performance due to Force Majeure. The Claiming Party will not be in breach of this Agreement or otherwise liable to the other Party (the "**Non-Claiming Party**") for any delay in performance or any non-performance of any obligations (except for payment obligations) under this Agreement (and the time for performance will be extended accordingly) if and to the extent that the delay or non-performance is owing to Force Majeure. Notwithstanding the foregoing, if Company is unable to manufacture and supply any Product pursuant to Clause 3 because of a Force Majeure as set forth in this Clause 12, Distributor shall be excused from all payment obligations with respect to the Purchase Order under which Company is unable to manufacture and supply the Product until such time Company resumes its obligations hereunder.

12.3 Notification. The Claiming Party shall promptly notify the Non-Claiming Party of the nature and extent of the circumstances giving rise to Force Majeure (in any event, within thirty (30) days), and shall promptly undertake and continue all

commercially reasonable efforts to cure such Force Majeure as soon as possible or to perform its obligations despite the ongoing Force Majeure.

12.4 Termination Due to Force Majeure. If the Force Majeure in question prevails for a continuous period in excess of one hundred and twenty (120) days after the date on which the Force Majeure begins, the Non-Claiming Party shall be entitled to give notice to the Claiming Party to terminate this Agreement. The notice to terminate must specify the termination date, which must be not less than thirty (30) days after the date on which the notice to terminate is given. Once a notice to terminate has been validly given pursuant to this Clause 12.4, this Agreement will terminate on the termination date set out in the notice. Neither party shall have any liability to the other Party in respect of termination of this Agreement due to Force Majeure, but rights and liabilities, which have accrued prior to termination, including payment obligations, shall subsist.

13. [*]

14. **DURATION AND TERMINATION**

14.1 Term. This Agreement shall commence on the Effective Date and continue in effect until the third (3rd) anniversary of the Commercial Activities Effective Date (the "**Initial Term**"), unless otherwise earlier terminated pursuant to this Agreement. This Agreement may be automatically renewed for additional one (1) year terms (each, a "**Renewal Term**" and collectively with the Initial Term, the "**Term**"), unless either Party provides written notice to the other Party of its intention to not renew at least one hundred eighty (180) days prior to the expiration of the then current Term.

14.2 Termination for Distributor Change of Control. Company shall be entitled to terminate this Agreement with immediate effect in the event of any Change of Control of Distributor that makes Company's Direct Competitor a newly controlling entity of Distributor.

14.3 Termination for Cause. Either Party shall be entitled to terminate this Agreement by written notice to the other Party in accordance with this Agreement if:

14.3.1 the other Party commits a breach of any material obligation under this Agreement, and in the case of a breach which is capable of remedy, the breaching Party fails to remedy such breach within thirty (30) days of the receipt of written notice from the non-breaching Party of such breach and of its intention to exercise its rights under this Clause 14.3.1. Where such breach is incapable of remedy within such thirty (30)-day cure period, the Parties shall discuss and may agree in good faith on a longer cure period;

14.3.2 the other Party becomes insolvent or bankrupt or subject to any winding up procedure, seeks a moratorium for the payment of its debts or files a similar petition to be placed under the protection of bankruptcy or insolvency laws, is subject to bankruptcy or similar proceedings as per the Applicable Law, or its assets are placed in whole or in part under supervision or control of a receiver, liquidator or similar officer; or

14.3.3 the other Party is the Claiming Party, pursuant to and in accordance with Clause 12.4.

14.4 No Waiver. Any waiver by either Party to avail itself of a breach of any provision of this Agreement shall not be considered as a waiver to avail itself of any subsequent breach of the same or any other provision thereof

14.5 Survival. The termination or expiration of this Agreement shall not release either of the Parties from any liability which at the time of termination or expiration, has already accrued to such Party, including payment obligations, nor affect in any way the survival of any other right, duty or obligation of the Parties which is expressly stated elsewhere in this Agreement to survive such termination or expiration. In addition, the Parties' rights and obligations under Clauses 1, 8, 9, 11.1, 11.2, 11.3, 11.4, 11.5, 12, 14.5 and 15 through 19 of this Agreement shall survive expiration or any termination of this Agreement.

## 15. CONSEQUENCES OF TERMINATION

15.1 Wind Down Period. Upon the expiration or termination of this Agreement for any reason, all licenses granted by Company to Distributor hereunder will automatically terminate, *provided* that (a) Distributor shall be permitted, for a period of six (6) months following the expiration or any termination of this Agreement, to Commercialize any stocks of the Products as Distributor may, as of the effective date of such expiration or termination, have in store or under its control and (b) thereafter, Company shall purchase from Distributor all remaining stocks of the Products as are of merchantable quality with a remaining shelf life of not less than six (6) months at the same price as was paid by Distributor for the Product and for its related carriage costs.

15.2 After Wind Down Period. Upon expiration of the six (6) month wind down period mentioned on Clause 15.1 above:

15.2.1 Distributor shall promptly return to Company or otherwise dispose of, as Company may instruct, all pamphlets, catalogues, advertising materials, specifications and other materials, documents or papers whatsoever sent to or created by Distributor and relating to the Products which Distributor may have in its possession or under its control;

15.2.2 Distributor shall immediately pay to Company any outstanding unpaid and undisputed invoices rendered in respect of the Product;

15.2.3 Distributor shall immediately cease the Commercialization of the Products;

15.2.4 destroy or return to Company any and all data, technical information or material relating to the Product. Distributor shall not under any circumstances and in any way, directly or indirectly, use such data, information or material in support of any product that competes with the Product;

15.2.5 Company shall destroy or return to Distributor, Distributor's Confidential Information in accordance with Clause 9.3. Company shall not, under any circumstances and in any way, directly or indirectly, use such data, information or material in support of any product that competes with the Product;

15.2.6 Distributor shall, as soon as reasonably practicable, and in any event within thirty (30) business days from Distributor's receipt of written request by Company, at Company's election, either (a) assign to Company or any designated third party (including an Affiliate of Company) all Subcontracting Agreements or (b) terminate all Subcontracting Agreements. For clarity, if any Subcontracting Agreement is assigned by Distributor to Company pursuant to the foregoing subclause (a), as of the effective date of such assignment and thereafter, Distributor shall not be responsible for the acts and omissions of the applicable Permitted Subcontractor.

15.3 No Further Obligations. Except as otherwise provided herein and for any rights or obligations which have accrued prior to termination or expiration (including payment obligations), neither Party shall have any further obligation to the other Party under this Agreement after the expiration or termination of this Agreement.

## 16. ASSIGNMENT; NON-SOLICITATION

16.1 Assignment. This Agreement is binding upon and will inure to the benefit of the Parties and their respective permitted assignees or successors in interest, including without limitation, those that may succeed by assignment, transfer or otherwise to the ownership of either of the Parties or of the assets necessary to the conduct of the business to which this Agreement relates. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned; *provided, however*, that either Party may, without such consent, assign this Agreement together with all of its rights and obligations hereunder (a) to its Affiliates or (b) to a successor in interest in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger or consolidation or similar transaction, in each case of (a) or (b), subject to the

assignee agreeing to be bound by the terms of this Agreement in writing, *provided, further* that the assigning Party must furnish to the other Party a prior written notice of any such assignment. Any purported assignment in violation of the preceding sentences shall be null and void. No assignment shall relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement. Any permitted successor shall assume and be bound by all obligations of its assignor or predecessor under this Agreement.

## 17. DISPUTE RESOLUTION

17.1 Escalation Procedures. Any dispute, controversy or claim between the Parties relating to this Agreement, including any dispute, controversy or claim regarding its execution, existence, validity, effectiveness, performance or termination (individually and collectively, "**Disputes**") that the Parties are not able to resolve within twenty (20) business days from the date that either Party notifies the other Party of the Dispute will be first referred to the Senior Officer of each Party. The Senior Officers of the Parties will make a good faith effort to resolve the Dispute within twenty (20) business days from the date of any such referral. If any Dispute cannot be resolved amicably by the Senior Officers of the Parties pursuant to this Clause 17.1, then upon the written demand of either Party to the other Party, the Dispute will be subject to arbitration in accordance with Clause 17.2.

17.2 Arbitration. In the event of a Dispute that cannot be resolved between the Parties or their Senior Officers as set forth in Clause 17.1, either Party will be free to institute binding arbitration with respect to such Dispute in accordance with this Clause 17.2 upon written notice to the other Party (an "**Arbitration Notice**") and seek remedies as may be available. Such binding arbitration shall be administered by JAMS (or any successor entity thereto) and in accordance with Streamlined Arbitration Rules & Procedures, or, if applicable, in accordance with the JAMS International Arbitration Rules, in each case, in accordance with the procedures set forth in this Clause 17.2. The seat of arbitration will be New York, New York and the language of the arbitration will be English. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute will be resolved by final and binding arbitration before one (1) arbitrator mutually selected by the Parties (the "**Arbitrator**"), with such Arbitrator having appropriate experience in the medical device industry and subject matter expertise with respect to the Dispute subject to arbitration. Such Arbitrator chosen hereunder will have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical, and industry knowledge relevant to the particular Dispute. The Parties' selection of such Arbitrator will in no event be made later than thirty (30) days after delivery of the Arbitration Notice. If the Parties are unable to mutually select the Arbitrator within such thirty (30)-day period, then either Party shall request JAMS to appoint the Arbitrator. The Arbitrator's decision and award will be made within ninety (90) days of the filing of the arbitration demand and the Arbitrator will agree to comply with this schedule before accepting appointment. However, this time limit may be extended by agreement of the Parties or by the Arbitrator. The Arbitrator will be authorized to award compensatory damages, but will not be authorized to reform, modify, or materially change this Agreement. The Arbitrator will, within fifteen (15) days after the conclusion of the hearing, issue a written award and statement of decision describing the material facts and the grounds for the conclusions on which the award is based, including the calculation of any damages awarded. The proceedings and decisions of the Arbitrator will be confidential, final, and binding on the Parties, and judgment upon the award of such Arbitrator may be entered in any court having jurisdiction

thereof. All costs associated with arbitration procedures set forth in this Clause 17.2 shall be borne (and reimbursed by) the losing Party.

17.3 Exceptions. Nothing in this Clause 17 will preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a Dispute either prior to or during any court proceedings, if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration.

## 18. NOTICES

18.1 Any notice given under this Agreement shall be in writing and delivered or sent by (a) registered or recorded delivery post or (b) email if followed up in writing sent by registered or recorded delivery post, in each case of (a) or (b), to the address or email address of the recipient Party as set out below (or such other address or email address as may have been notified in writing by the recipient Party), and any such notice shall be deemed to have been served (i) at the time of delivery (if delivered) or (ii) upon the expiration of five (5) business days after posting (if sent by post).

To the Company
Address:
DIXI Medical USA Corp
11910 Fox Ridge Dr
Plymouth, MI 48170
Attention: Mark Lemko
E-mail: [*]
With copies to: Frederic Koehn
Email: [*]

To the Distributor
Address:
NeuroPace, Inc.
455 Bernardo Ave
Mountain View, CA 94043
Attention: Mike Favet
E-mail: [*]
With copies to: Irina Ridley
Email: [*]

19. **GENERAL PROVISIONS**

19.1 Governing Law. This Agreement and the obligations of the Parties shall be governed by and construed in accordance with the laws of the State of New York, including its statutes of limitations without giving effect to the conflicts of law provisions thereunder. Any communication or proceedings resulting of disputes under this Agreement shall be in English language.

19.2 Amendments. No variation or amendment to the terms of this Agreement shall be effective unless in writing and signed on behalf of each Party by a director or other authorized Person specifically referencing this Agreement.

19.3 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part. The Parties shall use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) in a way that, to the extent practicable and legally permissible, implements the original intent of the Parties.

19.4 No Waiver of Rights. Failure by either Party on one or more occasions to avail itself of a right conferred by this Agreement shall not be construed as a waiver of such Party's right to enforce such right or any other right. The exercise by any Party of any right or election under the terms or covenants herein shall not preclude or prejudice any Party from exercising the same or any other right it may have under this Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

19.5 Entire Agreement. This Agreement (together with its Schedules, Appendices, Commercialization Plans, QA Requirements Documents and Commercial Support Requirements) constitutes the final, complete and exclusive agreement, and contains the entire agreement and understanding of the Parties respecting the subject matter hereof and cancels and supersedes any and all prior and

contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. Notwithstanding the foregoing, to the extent the terms and conditions of the body of this Agreement conflict with the terms and conditions of any Schedule or Appendix hereto, the terms and conditions of the body of this Agreement shall govern; *provided* that on matters of quality and release issues, GDP and GMP, the QA Requirements Document shall prevail. No terms or provisions of this Agreement will be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement. Each Party acknowledges that, in entering into this Agreement, it does not do so on the basis of and does not rely on any representation or warranty (whether made orally or in writing) except as expressly provided in this Agreement.

19.6 Independent Contractors. It is expressly agreed that Company and Distributor shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Company nor Distributor shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

19.7 No Third Party Beneficiaries. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

19.8 Successors and Assigns. Subject to the provisions of Clause 16.1, this Agreement shall inure to the benefit of, and be binding upon, the respective permitted assignees and successors of the Parties.

19.9 Public Announcement. No announcement, news release, public statement, publication or presentation relating to the existence of this Agreement, or the terms hereof or thereof, will be made without the other Party's prior written approval, which approval shall not be unreasonably withheld. The Parties each agree that once approval for disclosure of information subject to this Clause 19.9 has been obtained, the Party that requested such approval shall be entitled to use such information substantially in the form initially presented without an obligation to seek further approval.

19.10 Rights Cumulative. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law or in equity.

19.11 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

19.12 Counterparts. This Agreement may be executed in any number of counterparts and by the Parties to it on separate counterparts, each of which is an original but all of which together constitute one and the same instrument. Signatures to this Agreement transmitted by email in "**portable document format**" or by any other electronic means, intended to preserve the original graphic or pictorial appearance of the Agreement, shall have the same effect as the physical delivery of the paper Agreement bearing the original signatures.

[*Remainder of Page Intentionally Left Blank; Signature Page Follows*]

**IN WITNESS WHEREOF**, this Agreement has been signed by the authorized representatives of the Parties on the Effective Date.

*SIGNED for and on behalf of Company*
DIXI Medical USA Corp
*/s/ Frederic Koehn*

Signature
By: Frederic Koehn
Title: Chairman

SIGNED *for and on behalf of Company*

DIXI Medical USA Corp
*/s/ Mark Lemko*

Signature
By: Mark Lemko
Title: CEO
*SIGNED for and on behalf of Distributor*
NeuroPace, Inc.

*/s/ Mike Favet*

Signature
By: Mike Favet
Title: President and CEO

**Exhibit 31.1**

**CERTIFICATIONS**

I, Michael Favet, certify that:

1. I have reviewed this Form 10-Q of NeuroPace, 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(s) 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;

   (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(s) 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 8, 2022

By: /s/ Michael Favet
Michael Favet
President and Chief Executive Officer

**Exhibit 31.2**

**CERTIFICATIONS**

I, Rebecca Kuhn, certify that:

1. I have reviewed this Form 10-Q of NeuroPace, 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(s) 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;

   (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(s) 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 8, 2022

By: /s/ Rebecca Kuhn

Rebecca Kuhn

Chief Financial Officer and Vice President, Finance and Administration (Principal Financial and Accounting Officer)

**Exhibit 32.1**

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Michael Favet, Chief Executive Officer of NeuroPace, Inc. (the "Company"), and Rebecca Kuhn, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

**1.** The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

**2.** The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 8, 2022

**In Witness Whereof**, the undersigned have set their hands hereto as of the 8th day of November 2022.

| | | | |
|---|---|---|---|
| By: | /s/ Michael Favet | By: | /s/ Rebecca Kuhn |
| | Michael Favet | | Rebecca Kuhn |
| | President and Chief Executive Officer | | Chief Financial Officer and Vice President, Finance and Administration (Principal Financial and Accounting Officer) |

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NeuroPace, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.