Filed pursuant to Rule 424(b)(4)
Registration No. 333-251804
and 333-252495

PROSPECTUS

HELIUS MEDICAL TECHNOLOGIES, INC.

647,772 Units consisting of shares of Class A common stock and warrants (and shares of Class A common stock underlying such warrants)

We are offering 647,772 Units, with each Unit consisting of one share of Class A common stock, par value $0.001 per share (the "common stock"), and one warrant to purchase 0.5 shares of our common stock (together with the shares of common stock underlying such warrants, the "Units") at a public offering price of $14.82 per Unit. Warrants included in the Units have an exercise price of $16.302 per whole share of common stock (the "Warrants"), or 110% of the price of each Unit sold in the offering.

The Units will not be certificated and the shares of common stock and Warrants comprising the Units are immediately separable and will be issued separately in this offering. The Warrants will be exercisable immediately upon issuance and will expire on the five year anniversary of the original issuance date.

Our common stock is listed on The Nasdaq Capital Market under the symbol "HSDT" and on the Toronto Stock Exchange, or TSX, under the symbol "HSM." See "Prospectus Summary—Recent Developments" in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market. We do not intend to list the Warrants to be sold in this offering on any stock exchange or other trading market.

Investing in our securities involves a high degree of risk. Before making any investment in our securities, you should read and carefully consider the risks described in this prospectus under the section of this prospectus entitled "Risk Factors" on page 7 of this prospectus.

	Per Unit (1)	Total
Public offering price	$ 14.82	$ 9,599,981
Underwriting discounts and commissions (2)	$ 1.19	$ 770,978
Proceeds, before expenses, to Helius Medical Technologies, Inc.	$13.634	$ 8,829,003

(1) The public offering price and underwriting discount in respect of the Units corresponds to (i) a public offering price per share of common stock of $14.81 ($13.6252 net of the underwriting discount) and (ii) a public offering price per Warrant of $0.01 ($0.0092 net of the underwriting discount).

(2) We have agreed to pay certain expenses of the underwriter in this offering. We refer you to "Underwriting" on page 121 for additional information regarding underwriting compensation.

Affiliates of our Interim Chief Executive Officer have indicated an interest in purchasing approximately $250,000 of our Units in this offering on the same terms and at the same price as the units sold to the public in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriter may determine to sell more, fewer or no units in this offering to affiliates of our Interim Chief Executive Officer, and affiliates of our Interim Chief Executive Officer may determine to purchase more, fewer or no units in this offering. The underwriter will receive the same underwriting discount on any units of common stock purchased by affiliates of our Interim Chief Executive Officer as they will on any other units sold to the public in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriter has the option to purchase up to (i) 97,164 additional shares of common stock, and/or (ii) additional Warrants to purchase up to 48,582 additional shares of common stock solely to cover over-allotments, if any, at the public offering price per share of common stock and the public offering price per Warrant set forth above less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock and/or Warrants, or any combination thereof, as determined by the underwriter, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock to be issued at closing and 15% of the Warrants. The over-allotment option is exercisable for 45 days from the date of this prospectus.

In addition, we have agreed to issue upon the closing of this offering to Ladenburg Thalmann & Co. Inc., as representative of the underwriters, warrants that will expire on the fifth anniversary of the commencement of sales in this offering entitling the representative to purchase 4.0% of the total number of shares of common stock sold in this offering. The registration statement of which this prospectus is a part also covers the underwriters' warrants and the shares of common stock issuable upon the exercise thereof. For additional information regarding our arrangement with the underwriters, please see "Underwriting" beginning on page 121.

The underwriter expects to deliver the securities being offered pursuant to this prospectus against payment therefor on or about February 1, 2021.

Sole Book-Running Manager

Ladenburg Thalmann

The date of this prospectus is January 28, 2021.

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You should rely only on the information contained in this prospectus and any free-writing prospectus that we authorize to be distributed to you. We have not, and the underwriter has not, authorized anyone to provide you with information different from or in addition to that contained in this prospectus or any related free-writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and are seeking offers to buy, the securities offered by this prospectus only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the securities. Our business, financial conditions, results of operations and prospects may have changed since that date. You should also read and consider the information in the documents to which we have referred you under the caption "Where You Can Find Additional Information" in this prospectus.

We have not, and the underwriter has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to the offering of the securities and distribution of this prospectus outside the United States. No sales of our securities under this prospectus will be made to a resident of Canada.

We obtained industry and market data used throughout this prospectus through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission ("SEC"). It omits some of the information contained in the registration statement and reference is made to the registration statement for further information with regard to us and the securities being offered hereby. You should review the information and exhibits in the registration statement for further information about us and the securities being offered hereby. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to the filings. You should review the complete document to evaluate these statements.

You should read this prospectus and the additional information described below under "Where You Can Find Additional Information" before making an investment decision. You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted, including Canada.

You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of such document. Our business, financial condition, results of operations and prospects may have changed since those date.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file reports, proxy statements and other information with the SEC in accordance with the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our reports, proxy statements and other information filed with the SEC are available free of charge to the public over the Internet at the SEC's website at http://www.sec.gov. These documents may also be accessed on our website at www.heliusmedical.com. We are not including the information on our website as a part of, nor incorporating it by reference into, this prospectus or the registration statement of which it forms a part.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our securities, you should read this entire prospectus carefully, including our financial statements and related notes, the information in the section "Risk Factors," and "Where You Can Find Additional Information." Unless otherwise specified or the context otherwise requires, references in this prospectus to the "Company," "Helius," "we," "us", and "our" refer to Helius Medical Technologies, Inc. and its wholly owned subsidiaries, Helius Medical, Inc., or HMI, Helius Medical Technologies (Canada), Inc., or HMC, Helius Canada Acquisition Ltd., or HCA, and Helius NeuroRehab, Inc., or HNR.

All trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Company Overview

We are a neurotech company focused on neurological wellness. Our purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself.

Our first product, known as the Portable Neuromodulation Stimulator, or PoNS™ ("PoNS"), is authorized for sale in Canada as a class II, non-implantable, medical device intended as a short term treatment (14 weeks) of gait deficit due to symptoms from multiple sclerosis ("MS"), and balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy, or the PoNS Treatment™ ("PoNS Treatment"). The PoNS is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for de novo classification and clearance by the U.S. Food and Drug Administration (the "FDA") as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment™ is currently not commercially available in the United States, the European Union or Australia.

Corporate History

NeuroHabilitation Corporation, or NHC, a Delaware corporation, incorporated on January 22, 2013, is involved in the medical device industry. In January 2013, HMI entered into an exclusive rights agreement whereby Advanced Neuro-Rehabilitation LLC, or ANR, granted NHC exclusive worldwide rights to ANR's trade secrets, knowhow and patent pending technology for a non-invasive means for delivering neurostimulation through the oral cavity, in exchange for a 50% equity investment in NHC and a 4% royalty of NHC's revenue collected from (a) the U.S. sales of products covered by any claim of the patent pending rights to end users and (b) services related to the therapy or use of such products in therapy services.

On June 13, 2014, we acquired a 100% interest in NHC pursuant to a plan of merger whereby our wholly-owned subsidiary was merged with and into NHC and all of the common shares in the capital of NHC were cancelled in consideration for the issuance of an aggregate of 201,714 shares of our common stock to the shareholders of NHC. NHC, which changed its name to Helius Medical, Inc. in December 2018, is now our wholly-owned subsidiary. Prior to the transaction we had no active business.

On January 31, 2019, we formed another wholly owned subsidiary, Helius NeuroRehab, Inc., a Delaware corporation. On October 10, 2019, we formed Helius Canada Acquisition Ltd., a company incorporated under the

federal laws of Canada and a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc., a company incorporated under the federal laws of Canada, which acquired Heuro Canada, Inc. from Health Tech Connex Inc. on October 30, 2019.

Recent Developments

October 2020 Private Placement

On October 26, 2020, the Company closed on a private placement of an aggregate of 187,646 shares of common stock and warrants to purchase an aggregate of 93,817 shares of common stock (the "October 2020 Private Placement") at a purchase price of $18.20 per unit, consisting of one share and a warrant to purchase 0.50 shares of common stock, resulting in gross proceeds of approximately $3.4 million, excluding the proceeds, if any, that the Company may receive in the future from the exercise of the warrants. The Company incurred $0.2 million in share issuance costs, including placement agent fees. The warrants have an initial exercise price of $15.82 per share and are exercisable for a period of three years from the date of issuance. The Company also issued warrants to the placement agent to purchase 961 shares of common stock, with an exercise price of $19.775 per share. An officer of the Company and affiliates of an officer and director of the Company participated in the private placement on the same terms and conditions as all other purchasers, except that they paid $18.354 per unit and their warrants have an exercise price of $16.1665 per share.

Pursuant to the securities purchase agreement for the October 2020 Private Placement, if we issue any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the October 2020 Private Placement, each purchaser who subscribed for at least $250,000 in the October 2020 Private Placement has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

Nasdaq Notice

On March 23, 2020, the Company received notice from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") that the bid price for the Company's common stock had closed below $1.00 per share for the prior 30-consecutive business day period and that the Company had been granted a 180-day grace period, through September 21, 2020, to regain compliance with Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Rule"). Thereafter, on April 17, 2020, the Company received an additional notice from the Staff indicating that Nasdaq had temporarily stayed enforcement of the Minimum Bid Price Rule through June 30, 2020 and, accordingly, the 180-day grace period applicable to the Company would not expire until December 3, 2020.

On December 4, 2020, the Company received notice from the Staff indicating that the Company was not eligible for an additional 180 day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that the Company's securities would be subject to delisting unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concludes and any extension granted by the Panel expires.

On January 15, 2021, the Company received notice from the Staff that the bid price deficiency of the Company had been cured, and that the Company was in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

Reverse Stock Split

At a special meeting of our stockholders on December 28, 2020, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-5 to 1-for-35 to be determined at the discretion of our Board of Directors, whereby each outstanding 5 to 35 shares would be combined, converted and changed into 1 share of our common stock, to enable the Company to comply with Nasdaq's continued listing requirements. Following such meeting, our board of directors approved a final reverse stock split ratio of 1-for-35. We filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on December 31, 2020, and our common stock began trading on a split-adjusted basis on the Nasdaq Capital Market and TSX on January 4, 2021. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts for all periods presented in this prospectus and the registration statement of which it forms a part have been retroactively adjusted to reflect the reverse stock split we previously effected on January 22, 2018 and for the reverse stock split effected on December 31, 2020.

Risk Factors Summary

Our business is subject to a number of risks that you should be aware of before making a decision to invest in our securities, as fully described under "Risk Factors" in this prospectus. The principal factors and uncertainties that make investing in our securities risky include, among others:

- We have a history of losses and may not achieve or sustain profitability in the future;
- We will require additional financing to carry out our plan of operations, and failure to obtain such financing may cause our business to fail;
- We currently only have one product candidate, the PoNS device, which is authorized for commercial distribution in Canada, and we have not obtained authorization to distribute the PoNS device commercially in the United States, Europe or Australia and may never obtain such authorization;
- We may encounter substantial delays in planned clinical trials, and planned clinical trials may fail to demonstrate the safety and efficacy of the PoNS device to the satisfaction of regulatory authorities;
- Generation of revenue related to the PoNS technology is dependent on the PoNS Treatment being prescribed by physicians in the United States and our ability to train physical therapists in the supervision of the use of the PoNS Treatment;
- Market awareness of the PoNS device is limited, and the neuromodulation market is new and uncertain;
- We face significant competition in our market;
- We are dependent on third-party scientists and research institutions, in part, for research and development and on third parties for the manufacture and distribution of our product;
- The COVID-19 pandemic and outbreaks of communicable diseases may continue to materially and adversely affect our business, financial condition and results of operations;
- Third parties may gain access to our technology if our intellectual property protection is insufficient;
- We may be subject to various litigation claims and legal proceedings, including intellectual property litigation, which may adversely affect our business;
- Commercialization of our product outside of Canada is dependent on obtaining market authorization from the FDA and foreign regulatory authorities, which will require significant time, research, development, and clinical study expenditures and ultimately may not be successful;

- Failure to secure contracts with workers' compensation and third-party administrators or rehabilitation clinics could have a negative impact on our sales and would have a material adverse effect on our business, financial condition and operating results;
- Failure to obtain a reimbursement code from the U.S. Department of Health and Human Services so that the PoNS device is covered by Medicare and Medicaid could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results;
- If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure;
- We face ongoing government scrutiny and regulation in connection with the development of product candidates and following marketing authorization;
- After commercialization, a product recall or the discovery of serious safety issues with our products could have a significant adverse impact on us; and
- We have been the victim of a cyber-related crime, and our controls may not be successful in avoiding future cyber-related crimes.

Corporate Information

Our principal executive offices are located at 642 Newtown Yardley Road, Suite 100, Newtown, PA 18940 and our telephone number is 215-944-6100. We maintain a corporate website at www.heliusmedical.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as its reasonably practicable after we electronically file such material with, or furnish such material to the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this prospectus or the registration statement of which it forms a part. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov.

The Offering	
Issuer	Helius Medical Technologies, Inc.
Units Offered	We are offering 647,772 Units. Each Unit consists of one share of common stock and a Warrant to purchase 0.5 shares of our common stock (together with the shares of common stock underlying such Warrants).
Offering Price per Unit	$14.82
Description of Warrants	The Warrants will be exercisable immediately upon issuance and will expire on the five year anniversary of the original issuance date and have an initial exercise price equal to $16.302 per share, or 110% of the price of each Unit sold in the offering, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock.
Description of Underwriters' Warrants	Upon the closing of this offering, we have agreed to issue to Ladenburg Thalmann & Co. Inc., as representative of the underwriters, warrants, that will expire on the fifth anniversary of the commencement of sales in this offering, entitling the representative to purchase 4.0% of the number of shares of common stock sold in this offering. The registration statement of which this prospectus is a part also covers the underwriters' warrants and the common shares issuable upon the exercise thereof. For additional information regarding our arrangement with the underwriters, please see "Underwriting."
Shares of common stock underlying the Warrants	323,886 shares.
Shares of common stock outstanding before this offering	1,566,163 shares as of January 11, 2021.
Shares of common stock to be outstanding after this offering	2,213,935 shares (2,537,821 shares if the Warrants sold in this offering are exercised in full).
Over-allotment option	We have granted the underwriter an option to purchase up to an additional 97,164 shares of common stock and/or Warrants to purchase up to 48,582 shares of common stock at the public offering price per share of common stock and the public offering price per Warrant set forth on the cover page hereto less the underwriting discounts and commission. This option is exercisable, in whole or in part, for a period of 45 days from the date of this prospectus.
Potential insider participation	Affiliates of our Interim Chief Executive Officer have indicated an interest in purchasing approximately $250,000 of our Units in this offering on the same terms and at the same price as the units sold to

	the public in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriter may determine to sell more, fewer or no Units in this offering to affiliates of our Interim Chief Executive Officer, and affiliates of our Interim Chief Executive Officer may determine to purchase more, fewer or no Units in this offering. The underwriter will receive the same underwriting discount on any Units purchased by affiliates of our Interim Chief Executive Officer as they will on any other Units sold to the public in this offering.
Market and Trading Symbol	Our common stock is listed on The Nasdaq Capital Market under the symbol "HSDT" and on the TSX under the symbol "HSM." See "—Recent Developments" above for important information about the listing of our common stock on The Nasdaq Capital Market. There is no established trading market for the Warrants being offered and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Warrants will be limited.
Use of Proceeds	We intend to use the net proceeds of this offering for funding operations, working capital and general corporate purposes. See "Use of Proceeds" herein.
No listing of Warrants	We do not intend to apply for listing of the Warrants on any securities exchange or trading system.
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the section of this prospectus entitled "Risk Factors" on page 7 of this prospectus for a discussion of factors to consider before deciding to invest in this offering.

Except as otherwise indicated, all information in this prospectus is based on 1,566,163 shares of common stock outstanding as of January 11, 2021 and excludes the shares of common stock being offered by this prospectus and issuable upon exercise of the Warrants and also excludes the following:

- 111,074 shares of common stock issuable upon the exercise of stock options outstanding as of January 11, 2021, at a weighted-average exercise price of US$156.23 per share;
- 191,921 shares of common stock issuable upon the exercise of warrants (excluding the Warrants) outstanding as of January 11, 2021, at a weighted-average exercise price of US$16.01, and 68,351 shares of common stock issuable upon the exercise of warrants outstanding as of January 11, 2021, at a weighted-average exercise price of CAD$428.75 (or US$335.28 based on the exchange rate on January 11, 2021); and
- 96,969 shares of common stock reserved for future issuance under our 2018 Omnibus Incentive Plan as of January 11, 2021.

All share and per share amounts for all periods presented in this prospectus and the registration statement of which it forms a part have been retroactively adjusted to reflect the reverse stock split we previously effected on January 22, 2018 and for the reverse stock split effected on December 31, 2020.

RISK FACTORS

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this prospectus. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We have incurred substantial net losses since our inception and anticipate that we will continue to incur substantial net losses for the foreseeable future. We may never achieve or sustain profitability.

We have incurred substantial net losses since our inception. For the years ended December 31, 2019 and 2018, we incurred a net loss of $9.8 million and $28.6 million, respectively, and used cash in operations of $21.0 million and $19.6 million, respectively. We have an accumulated deficit of $104.8 million as of December 31, 2019. For the nine months ended September 30, 2020, we incurred a net loss of $11.4 million and used cash in operations of $9.6 million. As of September 30, 2020, our accumulated deficit was $116.4 million. Our losses have resulted primarily from costs incurred in connection with our design, manufacturing and development activities, research and development activities, building our commercial infrastructure, stock-based compensation, legal, advertising, marketing and investor relations, and general and administrative expenses associated with our operations. While we have received a medical device license from Health Canada to market the PoNS device in Canada, and even if we are successful in obtaining marketing authorization from the FDA in order to launch our PoNS device in the United States or additional foreign regulatory authorities to launch outside of the United States, we expect to continue to incur substantial losses for the foreseeable future as we continue to research and develop and seek regulatory marketing authorization for our product candidate.

We are subject to all of the business risks and uncertainties associated with any new business enterprise, including under-capitalization, cash shortages, limitations with respect to personnel, financial and other resources, lack of significant revenue and the risk that we will not achieve our growth objective. If sales revenue from any product candidate that receives marketing authorization from the FDA or other regulatory body is insufficient, if we are unable to develop and commercialize any of our potential product candidates, or if our product development is delayed, we may never achieve or sustain profitability.

We will require additional financing to carry out our plan of operations and if we are unable to obtain such financing, our business may fail.

We currently have limited working capital and liquid assets. We had cash of $5.5 million and $2.7 million at December 31, 2019 and September 30, 2020, respectively. To date we have not generated significant revenue from the commercial sale of products or services. There are a number of conditions that we must satisfy before we will be able to generate significant revenue, including but not limited to FDA marketing authorization of the PoNS device, manufacturing of a commercially-viable version of the PoNS device, obtaining favorable reimbursement from third party payers, and demonstration of effectiveness sufficient to generate commercial orders by customers for our product. We do not currently have sufficient resources to accomplish all of these conditions necessary for us to generate significant revenue, and we believe our existing capital resources, prior to the offering to which this prospectus relates, will be sufficient to fund our operations throughout the first quarter of 2021. We will therefore require substantial additional funds in order to continue to conduct the research and development and regulatory authorization activities necessary to bring our product to market, to establish effective marketing and sales capabilities and to develop other product candidates. We may never succeed in achieving regulatory authorization for our current product candidate in the United States, Europe or Australia.

We may be unable to raise the additional funding to finance our business on commercially reasonable terms, or at all. If we are unable to obtain additional financing as needed, we may be forced to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our company, which would have a material adverse effect on the value of our common stock.

Raising additional capital by issuing securities or through debt financings or licensing arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidate on terms unfavorable to us.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidate, future revenue streams, research programs or product candidate, or otherwise grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidate or our preclinical product candidates, or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to continue to operate without the threat of liquidation for the foreseeable future.

In connection with our management's assessment, our report from our independent registered public accounting firm for the fiscal year ended December 31, 2019 includes an explanatory paragraph stating that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. We believe our existing capital resources, prior to the offering to which this prospectus relates, will be sufficient to fund our operations throughout the first quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect our expenses to increase over time in connection with our ongoing activities, particularly if and as we: invest in marketing and distribution capabilities in support of potentially commercializing our PoNS device in the U.S., if approved; make improvements to our manufacturing process and product design; launch the TBI-002 trial or conduct other trials of the PoNS device; pursue further regulatory approvals; maintain, expand and protect our intellectual property portfolio; and add additional personnel. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors will likely lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Risks Related to the Development and Commercialization of our Product Candidate

We currently only have one product candidate, which is still in development, and we have not obtained authorization from the FDA to commercially distribute the device in the United States, a CE Mark for commercial distribution in Europe or from the TGA for commercial distribution in Australia, and we may never obtain such authorizations.

We currently have no products authorized for commercial distribution in either the United States, Europe or Australia or in any other country outside of Canada. We are developing the PoNS device for use in the neuromodulation market, but we cannot begin marketing and selling the device in the United States, Europe or Australia until we obtain applicable authorizations from the FDA, European Union (Notified Body) or Therapeutic Goods Administration in Australia, respectively. While we have submitted applications for regulatory marketing authorization in the United States and Australia, the process of obtaining regulatory authorization is expensive and time-consuming and can vary substantially based upon, among other things, the type, complexity and novelty of a product. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the authorization of a product candidate or rejection of a regulatory application altogether.

In April 2019, the FDA declined our request for de novo classification of the PoNS device for use to improve balance in patients with mmTBI. In reaching its conclusion, the FDA noted that it did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy to establish sufficient evidence of effectiveness based on our clinical trials. In October 2019, we had a pre-submission meeting where the FDA provided feedback needed to help complete the design of a new clinical trial intended to address the FDA's request for a trial that demonstrates the benefit of the PoNS Treatment compared to physical therapy alone. In January 2020, we received the FDA's feedback on the minutes from the October 2019 pre-submission meeting. In its feedback, the FDA provided post-meeting notes with specific recommendations regarding the trial design that were not discussed in the October 2019 pre-submission meeting. Based on the receipt of the FDA's final minutes from the pre-submission meeting, we finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. The launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. On May 7, 2020 we received Breakthrough Designation for the PoNS device as a potential treatment for gait deficit due to symptoms of MS, to be used as an adjunct to a supervised therapeutic exercise program. On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to the Company's request for de novo classification and clearance of the PoNS device, which includes requests for additional analysis of clinical data and proposes certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

The FDA has substantial discretion in the de novo review process and may refuse to accept our application or may decide that our data are insufficient to grant the de novo request and require additional pre-clinical, clinical, or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit, or prevent marketing authorization from the FDA or other regulatory authorities. Any marketing authorization from the FDA we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the product candidate not commercially viable. If our attempts to obtain marketing authorization are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, and results of operations will be materially adversely affected.

If we are able to complete development of the PoNS device and obtain marketing authorization of the PoNS device for the treatment of gait deficit in patients with MS in the United States, Europe or Australia, we plan to develop the PoNS device for other indications, or symptoms caused by neurological disorders. We would be required to commit our own resources to fund development of any other indications and each would require separate FDA clearance or other marketing authorization. The costs of such development efforts and FDA clearance or other marketing authorization could be substantial and would likely require additional funding, and each such indication would be subject to the same foregoing risks and uncertainties for FDA clearance/authorization.

The COVID-19 pandemic has adversely impacted, and may continue to materially and adversely impact, our business, financial condition and results of operations.

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS-authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures have been able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, they are all currently operating at reduced capacity within provincial guidelines, which limited operations to 50% capacity during the second half of 2020. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 has led to further restrictions on clinic activities. Additionally, while we do not currently have any clinical trials underway, we are running clinical experience programs in Canada and have experienced delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff, leading to further delays in the development and approval of the Company's product candidate. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

The COVID-19 pandemic and other outbreaks may cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device, and in the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in the development and manufacturing of our product. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

As the COVID-19 pandemic continues, we may experience additional disruptions that could severely impact our business and planned clinical trials including:

- Diversion of healthcare resources away from the conduct on clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- Interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitation on travel imposed or recommended by federal or state governments, employers and others;
- Delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- Changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the way in which clinical trials are conducted and may result in unexpected costs;
- Delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- Delay in the timing of our interactions with the FDA due to absenteeism by federal employees or the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19.

In addition to the risks specifically described above, the COVID-19 pandemic has exacerbated and precipitated the other risks described herein, and may continue to do so. The extent to which the COVID-19 pandemic will continue to impact the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. The Company does not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

Our PoNS technology is a novel form of neurostimulation therapy, and the medical community tends not to adopt new therapies very rapidly. If physicians elect not to prescribe the PoNS Treatment, or if we cannot train physical therapists in the supervision of the use of the PoNS Treatment, we will be unable to generate significant revenue, if any.

Our deployment strategy in the United States depends on physicians prescribing the PoNS Treatment to patients with relevant neurological disorders and physical therapists being trained in the supervision of patients' use of our treatment. Novel technologies are usually more slowly adopted by the medical community, as the medical community tends to be very conservative. Physicians may elect not to use our products for a variety of reasons, including:

- lack or perceived lack of evidence supporting the beneficial characteristics of our technology;
- limited long-term data on the use of PoNS technology for therapy;
- physicians' perception that there are insufficient advantages of our product relative to currently available products or compared to physical therapy alone;
- our inability to effectively train physical therapists in the supervision of patients' use of the therapy;
- our ability to develop our commercial infrastructure to successfully launch;
- hospitals may choose not to purchase our product;
- group purchasing organizations may choose not to contract for our product, thus limiting availability of our products to hospital purchasers;
- lack of coverage or adequate payment from managed care plans and other third-party payers for our product;

- Medicare, Medicaid or other third-party payers may limit or not permit reimbursement for our product; and
- the development or improvement of competitive products.

If the medical community is slow to adopt, or declines to adopt our PoNS device for neurostimulation therapy, we will not be able to generate significant revenues, if any, which would have a material adverse effect on our business.

There is limited market awareness of our product, and the neuromodulation market is new and uncertain.

There is currently limited market awareness of our product. In order to succeed, we must, among other things, increase market awareness of our PoNS Treatment and implement a sales and marketing strategy. If we fail in any of these endeavors or experience delays in pursuing them, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated. In addition, if the neuromodulation market fails to become more integrated in neurological therapy, it could have a materially adverse effect on our business and financial position.

We face significant competition in an environment of rapid technological change, and our competitors may develop devices or products that are more advanced or more effective than ours are which may adversely affect our financial condition and our ability to successfully market the PoNS device.

The neurostimulation market involves rapidly developing technology. Our competitors in the industry are predominantly large companies with longer operating histories, with significantly easier access to capital and other resources and an established product pipeline than us. The combined clinical research and product development done by the industry, including by us and all of our competitors, is foundational, and neurostimulation has slowly become integrated into neurological therapy. This foundation has allowed new and innovative neurostimulation companies to enter the market. New developments occur rapidly, and we anticipate that we will face increasing competition as new companies enter our market.

There can be no assurance that we will be able to establish ourselves in the neurostimulation market, or, if established, that we will be able to maintain our market position, if any. Our commercial opportunity may be reduced if our competitors develop new or improved products that are more convenient, more effective or less expensive than our product candidate is. Competitors also may obtain FDA or other regulatory marketing authorization for their products more rapidly or earlier than we may obtain marketing authorization for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render the PoNS device uneconomical or obsolete.

Risks Related to our Reliance on Third Parties

We are, and will continue to be, dependent in significant part on outside scientists and third-party research institutions for our research and development in order to be able to commercialize our product candidate.

We currently have a limited number of employees and resources available to perform the research and development necessary to commercialize our PoNS Treatment and potential future product candidates. We therefore rely, and will continue to rely, on third-party research institutions, collaborators and consultants for this capability.

We depend on third parties for the manufacture and distribution of our product and the loss of our third-party manufacturer and distributor could harm our business.

We depend on our third-party contract manufacturing partner to manufacture and supply our PoNS device for clinical and commercial purposes, and this contract manufacturer manufactured the units for our engineering

and device verification testing and is building the launch quantities for commercialization. Additionally, we depend on a different third-party distribution partner to warehouse and ship our products to customers. Our reliance on a third-party manufacturer and a distribution provider to supply us with our PoNS device and to provide such other distribution services exposes us to risks that could delay our sales or result in higher costs or lost product revenues. In addition, our manufacturers could encounter difficulties, including, but not limited to, those caused by the COVID-19 pandemic, in securing long-lead time components, achieving volume production, quality control and quality assurance or suffer shortages of qualified personnel, which could result in their inability to manufacture sufficient quantities of our commercially available product to meet market demand. Our third-party manufacturer or distributor may also fail to follow and remain in compliance with the FDA-mandated Quality System Regulations, or QSR, compliance which is required for all medical devices, or fail to document their compliance to QSRs, either of which could lead to significant delays in the availability of materials for our product and/or FDA enforcement actions against them and/or us.

If we are unable to obtain adequate supplies of our product that meet our specifications and quality standards, it will be difficult for us to compete effectively. While we have supply and quality agreements in place with our manufacturer, they may change the terms of our future orders or choose not to supply us with products in the future. Furthermore, if such manufacturer fails to perform its obligations, we may be forced to purchase our product from other third-party manufacturers, which we may not be able to do on reasonable terms or in sufficient time, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer or the reverification of an existing manufacturer could negatively affect our ability to produce and distribute our product in a timely manner.

In order to be successful, we must expand our product lines beyond our PoNS Treatment for gait deficit due to symptoms from MS or balance deficit due to mmTBI, but we may not be able to do so in a timely fashion and at expected costs, or at all.

In order to be successful, we will need to expand our product lines beyond our PoNS Treatment for gait deficit due to symptoms from MS or balance deficit due to mmTBI. To succeed in our commercialization efforts, we must effectively continue product development and testing, obtain regulatory authorizations, and enhance our sales, marketing and market access and reimbursement capabilities. There is no assurance that we will succeed in developing a future product candidate or in bringing any of our current or potential future product candidates to market outside of Canada. If we fail in bringing our product candidates to market, or experience delays in doing so, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

The development of additional products is subject to the risks of failure inherent in the development of new, state of the art products, and products based on new technologies. These risks include: (a) delays in product development or manufacturing; (b) unplanned expenditures for product development or manufacturing; (c) failure of new products to have the desired effect or an acceptable accuracy and/or safety profile; (d) emergence of superior or equivalent products; (e) failure by any potential collaborative partners to successfully develop products; and (f) the dependence on third parties for the manufacture, development and sale of our products. Because of these risks, our research and development efforts or those of potential collaborative partners may not result in any commercially viable products. If a significant portion of these development efforts is not successfully completed, or any products are not commercially successful, we are less likely to generate significant revenues, or become profitable. The failure to perform such activities could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Intellectual Property

If our intellectual property protection is inadequate, competitors may gain access to our technology and undermine our competitive position.

We regard our intended and future intellectual property as important to our success, and we intend to rely on patent law to protect our proprietary rights. Despite our precautions, unauthorized third parties may copy certain portions of our devices or products or reverse engineer or obtain and use information that we regard as proprietary. We may seek additional patents in the future. We do not know if any future patent application will be issued with the scope of the claims, we seek, if at all or whether any patents we receive will be challenged or invalidated. Thus, we cannot assure you that any intellectual property rights that we may receive can be successfully asserted in the future or that they will not be invalidated, circumvented or challenged. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent, as do the laws of the United States. Our means of protecting any proprietary rights we may receive in the United States or abroad may not be adequate and competitors may independently develop a similar technology. Any failure to protect our proprietary information and any successful intellectual property challenges or infringement proceedings against us could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to various litigation claims and legal proceedings, including intellectual property litigation, such as patent infringement claims, which could adversely affect our business.

We, as well as certain of our directors and officers, may be subject to claims or lawsuits. These lawsuits may result in significant legal fees and expenses and could divert management's time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines. Any of these outcomes could cause our business, financial performance and cash position to be negatively impacted.

Additionally, our commercial success will also depend, in part, on not infringing on the patents or proprietary rights of others. There can be no assurance that the technologies and products used or developed by us will not infringe such rights. If such infringement occurs and we are not able to obtain a license from the relevant third party, we will not be able to continue the development, manufacture, use, or sale of any such infringing technology or product. There can be no assurance that necessary licenses to third-party technology will be available at all or on commercially reasonable terms. In some cases, litigation or other proceedings may be necessary to defend against or assert claims of infringement or to determine the scope and validity of the proprietary rights of third parties. Any potential litigation could result in substantial costs to, and diversion of, our resources and could have a material and adverse impact on us.

An adverse outcome in any such litigation or proceeding could subject us to significant liabilities, require us to cease using the subject technology or require us to license the subject technology from the third party, all of which could have a material adverse effect on our business.

There are risks to our intellectual property based on our international business operations.

We may face risks to our technology and intellectual property as a result of our conducting business outside of the United States, including as a result of our strategic agreement with A&B (and subsequent transfer of assets to CMS and CMS Medical Hong Kong Limited), and particularly in jurisdictions that do not have comparable levels of protection of corporate proprietary information and assets such as intellectual property, trademarks, trade secrets, know-how and customer information and records. While these risks are common to many companies, conducting business in certain foreign jurisdictions, housing technology, data and intellectual property abroad, or licensing technology to joint ventures with foreign partners may have more significant exposure. Pursuant to our agreement with A&B, we transferred ownership of certain of our Asian patents, patent applications, and product support material for the PoNS device from us to A&B and granted to A&B, among

other things, an exclusive license to market, promote, distribute and sell the PoNS device solely within specified Asian territories. Subsequently. A&B partnered with other companies in other foreign jurisdictions in connection with the development and manufacturing of the PoNS device, which may expose us to material risks of theft of our proprietary information and other intellectual property, including technical data, manufacturing processes, data sets or other sensitive information. For example, our product or components may be reverse engineered by other business partners or other parties, which could result in our patents being infringed or our know-how or trade secrets stolen. The risk can be by direct intrusion wherein technology and intellectual property is stolen or compromised through cyber intrusions or physical theft through corporate espionage, including with the assistance of insiders, or via more indirect routes.

Risks Related to Government Regulation

Before we can market and sell our products, we will be required to obtain marketing authorization from the FDA and foreign regulatory authorities. These authorizations will take significant time and require significant research, development, and clinical study expenditures, and ultimately may not succeed.

Before we begin to label and market the PoNS Treatment for use in the United States, we are required to obtain marketing authorization via a de novo classification and clearance request for our product or approval of pre-market approval application from the FDA, unless an exemption from pre-market review applies. We will also be required to comply with costly and more often time-consuming regulatory requirements by foreign regulatory authorities, including Europe and Australia, if we want to sell our products outside of the United States, other than Canada, where PoNS Treatment is authorized for sale as a class II, non-implantable, medical device for treatment of gait deficit due to symptoms from MS and balance deficit due to mmTBI in conjunction with physical therapy. The process of obtaining regulatory authorizations or approvals, including completion of the de novo classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

In April 2019, the FDA declined our request for de novo classification of the PoNS device for use to improve balance in patients with mmTBI. In reaching its conclusion, the FDA noted that it did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy to establish sufficient evidence of effectiveness based on our clinical trials. In October 2019, we had a pre-submission meeting where the FDA provided feedback needed to help complete the design of a new clinical trial intended to address the FDA's request for a trial that demonstrates the benefit of the PoNS Treatment compared to physical therapy alone. In January 2020, we received the FDA's feedback on the minutes from the October 2019 pre-submission meeting. In its feedback, the FDA provided post-meeting notes with specific recommendations regarding the trial design that were not discussed in the October 2019 pre-submission meeting. Based on the receipt of the FDA's final minutes from the pre-submission meeting, we finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. The launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. On May 7, 2020 we received Breakthrough Designation for the PoNS device as a potential treatment for gait deficit due to symptoms of MS, to be used as an adjunct to a supervised therapeutic exercise program. On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to the Company's request for de novo classification and clearance of the PoNS device, which includes requests for additional analysis of clinical data and proposes certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

The FDA has substantial discretion in the de novo review process and may refuse to accept our application or may decide that our data are insufficient to grant the de novo request and require additional pre-clinical, clinical, or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit, or prevent marketing authorization from the FDA or other regulatory authorities.

If the FDA requires us to go through a lengthier, more rigorous examination for the PoNS device for MS or any other indication we may pursue, introducing the product could be delayed or canceled, which would cause our launch to be delayed or cancelled. In addition, the FDA may determine that the PoNS device requires the more costly, lengthy and uncertain pre-market approval process. For example, if the FDA disagrees with our determination that the de novo classification procedures are the appropriate path to obtain marketing authorization for the PoNS device, the FDA may require us to submit a PMA application, which is generally more costly and more burdensome and can take several years from the time the application is submitted to the FDA until an approval is obtained.

Moreover, in addition to continuing our pursuit of an indication for mmTBI with FDA, we are currently considering the development of the PoNS device for other potential indications, including stroke, cerebral palsy, Parkinson's disease, baby boomers balance, and neurological wellness, as well as expanding the label of our current indications. At this time, we do not know what pathways the FDA or other regulatory authorities will require us to utilize for these additional indications. We may be required to pursue marketing authorization via more rigorous pathways, such as a PMA application in the United States, which may require more development work than we are currently planning. This would delay the potential marketing authorization for such indications, potentially make marketing authorization more difficult to obtain, and increase our costs.

Obtaining FDA marketing authorization will be costly, may result in time-consuming delays and will subject us to ongoing compliance costs and regulatory risk for non-compliance.

Obtaining FDA marketing authorization, de novo classification and clearance, or PMA approval for medical devices can be expensive and uncertain, generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA authorization. Even if we were to obtain regulatory authorization, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

The FDA can delay, limit or deny authorization of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our product candidate is safe and effective for its intended users;
- the data from our pre-clinical studies and clinical trials may be insufficient to support authorization, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its authorization policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of our products under development. Any delay in, or failure to receive or maintain clearance or approval for our product candidate could prevent us from generating revenue from our product candidate and adversely affect our business operations and financial results.

Even if granted, a 510(k) clearance, de novo classification and clearance, or pre-market approval for any future product would likely place substantial restrictions on how our device is marketed or sold, and FDA will continue to place considerable restrictions on our products and operations. For example, the manufacture of medical devices must comply with FDA's QSR. In addition, manufacturers must register their manufacturing facilities, list the products with FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and

export. FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications of repair, replacement, refunds, detention or seizure of our products;
- product recalls;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for marketing authorization of new products or modified products;
- withdrawing marketing authorizations that have already been granted;
- refusing to provide Certificates for Foreign Government;
- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our product candidate and dissuade our customers from using our product candidate, if and when it is authorized for marketing.

We may be required to conduct clinical trials to support a future de novo submission or PMA application for the PoNS device and we expect to be required to conduct clinical trials to support regulatory marketing authorization for future product candidates.

In order to commercialize our product candidate in the United States, we may be required by the FDA to submit an application for premarket approval, or PMA, for review and approval by the FDA. A PMA application must be submitted to the FDA if our device cannot be cleared through the 510(k) clearance process, down classified via the de novo process, or is not exempt from premarket review by the FDA. In April 2019, the FDA declined our request for de novo classification and clearance for mmTBI. Following a pre-submission meeting with the FDA, we finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. The launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. On May 7, 2020 we received Breakthrough Designation for the PoNS device as a potential treatment for gait deficit due to symptoms of MS, to be used as an adjunct to a supervised therapeutic exercise program. On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to the Company's request for de novo classification and clearance of the PoNS device, which includes requests for additional analysis of clinical data and proposes certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

We could also be required to submit a PMA application for potential future product candidates. If we are required by the FDA to submit a PMA application, the FDA will also require us to conduct clinical trials. We will receive marketing authorization from the FDA to commercialize products requiring a clinical trial only if we can demonstrate to the satisfaction of the FDA, through well designed and properly conducted clinical trials, that our product candidate is safe, effective, and otherwise meet the appropriate standards required for marketing authorization for specified indications.

We have and may continue to encounter substantial delays in planned clinical trials, or our planned clinical trials for other indications using the PoNS device may fail to demonstrate the safety and efficacy of the PoNS device to the satisfaction of applicable regulatory authorities.

As described above, following the FDA's denial of our request for de novo classification and clearance for mmTBI in April 2019, we finalized our clinical protocol for TBI-002 intended to support a request for de novo classification and clearance of the PoNS device for mmTBI. Prior to the COVID-19 pandemic, our expectation was that we would move forward with the revised protocol and estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

While we currently have no ongoing clinical trials, but we expect that we will need to conduct further clinical trials, including the TBI-002 trial if we continue to pursue de novo classification and clearance for mmTBI in the United States. Clinical trials are complex, expensive, time consuming, uncertain as to outcome and are subject to substantial and unanticipated delays. Before we may begin clinical trials, if a clinical trial is determined to present a significant risk, we may be required to submit and obtain approval for an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials generally involve a substantial number of patients in a multi-year study. Because we do not have the infrastructure necessary to conduct clinical trials, we will have to hire one or more contract research organizations, or CROs, to conduct trials on our behalf. CRO contract negotiations may be costly and time consuming and we will rely heavily on the CRO to ensure that our trials are conducted in accordance with regulatory and industry standards. We may encounter problems with our clinical trials and any of those problems could cause us or the FDA to suspend those trials or delay the analysis of the data derived from them. Moreover, any failure to abide by the applicable regulatory requirements by us, our CROs, and/or clinical trial sites may result in regulatory enforcement action against such third parties or us.

We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Delays, including, but not limited those caused by the COVID-19 pandemic, can be costly and could negatively affect our ability to complete a clinical trial and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize the PoNS device. If we are unable to complete such planned clinical trials, or are unsuccessful in doing so, we may be unable to advance the PoNS device to regulatory authorization and commercialization, which would harm our business, financial condition, results of operations.

We may be substantially dependent on third parties to conduct our clinical trials.

Since we may conduct clinical trials to obtain FDA marketing authorization, we will need to rely heavily on third parties over the course of our clinical trials, and as a result will have limited control over the clinical investigators and limited visibility into their day-to-day activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. These third parties and we are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in

clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical or clinical trials before approving our marketing applications or may subject them or us to regulatory enforcement actions. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials may be required to be conducted with a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory marketing authorization process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory marketing authorization of or successfully commercialize our product candidate. As a result, our financial results and the commercial prospects for our product candidate would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If any of our relationships terminate with these third-party CROs, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We may be required to suspend or discontinue clinical trials due to side effects or other safety risks that could preclude approval of our products.

Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to participants.

If we are unable to secure contracts with WC and third-party administrators or rehabilitation clinics who treat patients with gait deficit due to symptoms from MS or balance issues associated with mmTBI, this could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results.

One of our commercialization strategies includes leveraging WC payers to drive early reimbursements and entice Medicaid and commercial payers through third-party administrators and rehabilitation clinics. Should we fail in securing such contracts it could have a material adverse effect on our intended sales projections, which would affect our financial conditions and operating results. In addition, until we are successful in engaging WC payers, Medicaid and other third-party commercial payers to cover the cost of the PoNS device for their insured

customers, we expect our initial sales of the PoNS device will be via cash paid by patients. As a result, we may not be able to sell our PoNS device in commercially reasonable quantities depending on the cost of the device to cash payers.

If we are unable to obtain a reimbursement code from the U.S. Department of Health and Human Services so that the PoNS device is covered under Medicare and Medicaid, this could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results.

We plan to submit an application to the U.S. Department of Health and Human Services for a reimbursement code so that the PoNS device is covered under Medicare and Medicaid. However, there can be no assurance that our application will be successful, or that we will be able to obtain a reimbursement code in a timely manner. In the event that we do not obtain a reimbursement code for the PoNS device, our customers may be unable to obtain reimbursement for their purchases under private or government-sponsored insurance plans, which could have a negative impact on our sales and have a material adverse effect on our business, financial condition and operating results. In addition, Medicare and its administrative contractors as well as other insurers must find that the PoNS device meets their medical necessity requirements for the treatment of patients with mmTBI or they will not pay for the treatment. In addition, there is a risk that the payment amount for the PoNS device is either too low or too high to incentivize customer adoption.

If hospitals and other healthcare providers are unable to obtain coverage or adequate reimbursement for procedures performed with our products, our product will not likely be widely used.

In the United States, the commercial success of our existing product and any future products will depend, in part, on the extent to which governmental payers at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for procedures utilizing our products. On January 12, 2021, the CMS stated that it is finalizing a new Medicare coverage pathway, Medicare Coverage of Innovative Technology, or "MCIT," for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. Manufacturers will be able to opt-in to MCIT and choose a start date for coverage anytime within two years from the date of FDA market authorization. Hospitals and other healthcare providers that purchase our product for treatment of their patients generally rely on third-party payers to pay for all or part of the costs and fees associated with our products as part of a "bundled" rate for the associated procedures. The existence of coverage and adequate reimbursement for our products and the procedures performed with them by government and private payers is critical to market acceptance of our existing and future products. Neither hospitals nor physicians are likely to use our product and any future products if they do not receive adequate reimbursement for the procedures utilizing our products.

Many private payers currently base their reimbursement policies on the coverage decisions and payment amounts determined by the CMS, which administers the Medicare program. Others may adopt different coverage or reimbursement policies for procedures performed with our products, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for the procedures performed with our products in an adequate amount, if at all. A Medicare national or local coverage decision denying coverage for one or more of our products could result in private and other third-party payers also denying coverage for our products. Third-party payers also may deny reimbursement for our products if they determine that a product used in a procedure was not medically necessary, was not used in accordance with cost-effective treatment methods, as determined by the third-party payer, or was used for an unapproved use. Unfavorable coverage or reimbursement decisions by government programs or private payers underscore the uncertainty that our product face in the market and could have a material adverse effect on our business.

Many hospitals and clinics in the United States belong to group purchasing organizations, which typically incentivize their hospital members to make a relatively large proportion of purchases from a limited number of vendors of similar products that have contracted to offer discounted prices. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key group purchasing organizations and/or persuade hospitals and clinics to purchase our product "off contract."

The healthcare industry in the United States has experienced a trend toward cost containment as government and private payers seek to control healthcare costs by paying service providers lower rates. While we believe that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Private payers frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payers are adopting pay-for-performance programs that differentiate payments to healthcare providers based on the achievement of documented quality-of-care metrics, cost efficiencies, or patient outcomes. These programs are intended to provide incentives to providers to deliver the same or better results while consuming fewer resources. Because of these programs, and related payer efforts to reduce payment levels, hospitals and other providers are seeking ways to reduce their costs, including the amounts they pay to medical device manufacturers. We may not be able to sell our product profitably if third-party payers deny or discontinue coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. Adverse changes in payment rates by payers to hospitals could adversely affect our ability to market, sell our products, and negatively affect our financial performance.

In international markets, medical device regulatory requirements and healthcare payment systems vary significantly from country to country, and many countries have instituted price ceilings on specific product lines. We cannot assure you that our products will be considered cost-effective by international third-party payers, that reimbursement will be available or, if available, that the third-party payers' reimbursement policies will not adversely affect our ability to sell our product profitably. Any failure to receive regulatory or reimbursement approvals would negatively affect market acceptance of our products in any international markets in which those approvals are being sought.

If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure, and our business, operations and financial condition could be adversely affected.

We do not have a product available for sale in the United States. If, however, we achieve this goal, the availability of payments from Medicare, Medicaid or other third-party payers would mean that many healthcare laws would place limitations and requirements on the manner in which we conduct our business, including our sales and promotional activities and interactions with healthcare professionals and facilities. In some instances, our interactions with healthcare professionals and facilities that occurred prior to commercialization (e.g., the granting of stock options) could have implications at a later date. The laws that may affect our ability to operate include, among others: (i) the federal healthcare programs Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us if we provide coding and billing advice to customers, or under theories of "implied certification" where the government and *qui tam* relators may allege that device companies are liable where a product that was paid for by the government in whole or in part was promoted "off-label," lacked necessary marketing authorization, or failed to comply with good manufacturing practices or other laws; (iii) transparency laws and related reporting and/or disclosures such

as the Sunshine Act; and/or (iv) state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of evolving interpretations and enforcement discretion. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Our communications regarding product candidates, even while in development, are subject to extensive government scrutiny. We may be subject to governmental, regulatory and other legal proceedings relative to advertising, promotion, and marketing, and communications with study subjects and healthcare professionals, which could have a significant negative effect on our business.

We are subject to governmental oversight and associated civil and criminal enforcement relating to medical device advertising, promotion, and marketing, and such enforcement is evolving and intensifying. Communications regarding our products in development and regarding our clinical trials may subject us to enforcement if they do not comply with applicable laws. In the United States, we are potentially subject to enforcement from the FDA, other divisions of the Department of Health and Human Services, the U.S. Federal Trade Commission, or the FTC, the Department of Justice, and state and local governments. Other parties, including private plaintiffs, also are commonly bringing suit against pharmaceutical and medical device companies. We may be subject to liability based on the actions of individual employees and third-party contractors carrying out activities on our behalf.

Even after marketing authorization for our product is obtained, we are subject to extensive post-market regulation by the FDA and equivalent foreign competent authorities. Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities.

Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-market studies. These studies can be very expensive and time-consuming to conduct. Failure to complete such studies in a timely manner could result in the revocation of clearance or approval and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States.

The FDA has broad enforcement powers, and any regulatory enforcement actions or inquiries, or other increased scrutiny on us, could dissuade some healthcare professionals from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

We are also required to comply with the FDA's Quality System Regulation, or QSR, which covers the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, installation and servicing of our marketed products.

The FDA enforces these requirements via periodic announced and unannounced inspections of manufacturing facilities. In addition, in the future, regulatory authorities and/or customers may require specific packaging of sterile products, which could increase our costs and the price of our products.

Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

After commercialization, a recall of our products, either voluntarily or at the direction of a governmental authority, or a foreign competent authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities such as the competent authorities of the European Economic Area countries or Health Canada have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiencies in our products are found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues.

The FDA requires that certain classifications of voluntary recalls of devices be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Any recalls of any of our products would divert managerial and financial resources and could have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Any future failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refund, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance, de novo clearance, PMA approval, NDA, or BLA of new products or modified products;
- withdrawing clearances or approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product and to manufacture, market and distribute our products after marketing authorization is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Risks Related to our Business Operations

If our expenses are greater than anticipated, then we will have fewer funds with which to pursue our plan of operations and our financing requirements will be greater than anticipated.

We may find that the costs of carrying out our plan of operations are greater than we anticipate. We expect our expenses to increase over time in connection with our ongoing activities, particularly if and as we: invest in marketing and distribution capabilities in support of potentially commercializing our PoNS device in the U.S., if approved; make improvements to our manufacturing process and product design; launch the TBI-002 trial or conduct other trials of the PoNS device; pursue further regulatory approvals; maintain, expand and protect our intellectual property portfolio; and add additional personnel. Increased operating costs may cause the amount of financing that we require to increase. Investors may be more reluctant to provide additional financing if we cannot demonstrate that we can control our operating costs. There is no assurance that additional financing required as a result of our operating costs being greater than anticipated will be available to us. If we do not control our operating expenses, then we will have fewer funds with which to carry out our plan of operations with the result that our business may fail.

We are heavily dependent upon the ability and expertise of our management team and a very limited number of employees and the loss of such individuals could have a material adverse effect on our business, operating results or financial condition.

We currently have a very small management team. Our success is dependent upon the ability, expertise and judgment of our senior management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on our business, operating results or financial condition.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, substantial changes in a corporation's ownership may limit the amount of net operating losses, or NOLs, that can be utilized annually in the future to offset the corporation's (and the corporation's affiliates') U.S. federal and state taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of more than 50% within any three-year period. The amount of the annual limitation is determined based on the value of the corporation that underwent the ownership change, immediately before the ownership change. Subsequent ownership changes may further affect any limitation in future years (including by way of exercising of warrants).

We may undertake a study to analyze and determine if any historical ownership changes of us or our subsidiary HMI have occurred to determine if there are any permanent limitations on our ability to utilize NOLs

in the future. If we determine that an ownership change has occurred, the limitations on the use of our NOLs could increase our U.S. federal and state tax liability and reduce the amount of cash available for distribution to shareholders or otherwise adversely affect the value of an investment in our common stock or warrants.

We may not be able to build an effective distribution network for our product.

We currently have very few employees and we may either build internal capabilities or rely on distributors to sell our product. We cannot assure you that we will succeed in building an internal team or entering into and maintaining productive arrangements with an adequate number of distributors that are sufficiently committed to selling our products. The establishment of a distribution network is expensive and time consuming. As we launch new products and increase our marketing effort with respect to existing products, we will need to continue to hire, train, retain and motivate skilled resources with significant technical knowledge. In addition, the commissions we pay for product sales could increase over time, which would result in higher sales and marketing expenses. Furthermore, if we were to rely on distributors, the current and potential distributors may market and sell the products of our competitors. Even if the distributors market and sell our product, our competitors may be able, by offering higher commission payments or other incentives, to persuade these distributors to reduce or terminate their sales and marketing efforts related to our product. The distributors may also help competitors solicit business from our existing customers. Some of our independent distributors may likely account for a significant portion of our sales volume, and, if we were to lose them, our sales could be adversely affected. Even if we engage and maintain suitable relationships with an adequate number of distributors, they may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products, or ultimately succeed in selling our product.

Exposure to United Kingdom political developments, including the outcome of the referendum on membership in the European Union, could be costly and difficult to comply with and could seriously harm our business.

In January 2020, the United Kingdom formally withdrew from the European Union, commonly referred to as “Brexit.” Brexit has created an uncertain political and economic environment in the United Kingdom and other European Union countries. The political and economic instability created by Brexit has caused and may continue to cause significant volatility in global financial markets and uncertainty regarding the regulation of data protection in the United Kingdom.

Brexit may have a significant negative impact on medical device manufacturers such as us. A Notified Body, or NB, that we contracted with as our EU regulatory service provider is located in the UK. CE Mark issued by a UK NB is at risk due to Brexit. Medical device manufacturers such as us with products CE Marked by a UK NB may not be able to place those products on the market until Brexit issues are resolved by the European Commission and local governments. In addition, the acceptance of medical device market authorization from UK NBs by countries outside of the EU, which have traditionally accepted UK NB CE marked products, is at risk of interruption due to Brexit. The complexity of Brexit places a significant burden on UK NBs which may negatively impact their ability to provide market clearance (i.e., CE Marking) reviews and certifications in a timely manner. Delays in CE Marking and delays in the issuance of certificates could delay us from placing our PoNS device on the market outside of the UK including outside of the EU (for those countries that require quality management system certificates and CE approval prior to marketing).

In December 2018, we submitted an application for a CE Mark, which, if approved, would allow us to market the PoNS device in the European Union. During the second quarter of 2019, we engaged with regulators in Europe to answer questions that we received from them as part of their review of our PoNS device for CE marking. In August 2019, we withdrew our application from the EU marketing process due to uncertainty in Europe caused by the switch from the Medical Device Directive, or MDD, to the Medical Device Regulation, or MDR, Brexit, and the withdrawal of Lloyd’s Register Quality Assurance, our notified body, from the EU notified body business. We have engaged G-MED NA (North America) as our new ISO registrar and new notified body and will reconsider submitting to the EU when conditions stabilize.

As a result of the use of our product candidates in clinical trials, and through the sale of our products, we may be liable for product liability claims and we may not carry sufficient product liability insurance.

The PoNS device and any devices and product candidates that we may develop in the future may expose us to potential liability from personal injury claims by clinical trial subjects and, if commercially sold, end-users of the product. We maintain clinical trial liability insurance and carry product liability insurance to protect us against the risk that in the future a product liability claim or product recall could materially and adversely affect our business. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our intended product. We cannot assure you that when we commence distribution of our product that we will be able to obtain or maintain adequate coverage on acceptable terms, or that such insurance will provide adequate coverage against all potential claims. Moreover, even if we maintain adequate insurance, any successful claim could materially and adversely affect our reputation and prospects and divert management's time and attention. If we are sued for any injury allegedly caused by our future products, our liability could exceed our total assets and our ability to pay the liability.

We are a "smaller reporting company" under federal securities laws and we cannot be certain whether the reduced reporting requirements applicable to such companies will make our common stock less attractive to investors.

We are a "smaller reporting company" under federal securities laws. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will remain a smaller reporting company so long as our public float remains less than $250 million as of the last business day of our most recently-completed second fiscal quarter. We cannot predict if investors will find our common stock less attractive because we may rely 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 decline or be more volatile.

Investors could lose confidence in our financial reports, and the value of our common stock may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm.

As long we remain a non-accelerated filer, we are exempt from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404(b) of the Sarbanes-Oxley Act of 2002 but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting. The existence of one or more material weaknesses, such as the material weakness we identified in October 2019, could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our common stock may be harmed, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm.

Several people who work for us on a part-time consulting basis may be subject to conflicts of interest.

Several people who provide services to us are part-time consultants. Each may devote part of his working time to other business endeavors, including consulting relationships with other corporate entities, and may have responsibilities to these other entities. Because of these relationships, some of the persons who provide services to us may be subject to conflicts of interest. Such conflicts may include deciding how much time to devote to our affairs, as well as what business opportunities should be presented to us.

We have been the victim of a cyber-related crime and our controls may not be successful in avoiding further cyber-related crimes in the future.

In October 2019, we were the victim of a business email compromise fraud which resulted in our incurring a loss of approximately $0.1 million. We are working with law enforcement authorities and the banks involved in the wire transfer to pursue recovery of the $0.1 million, but at this time while law enforcement officials have identified the source of the scam, we do not know whether we will be able to recover any of the funds, and we have been advised that it may take several months before we are better able to evaluate our recovery prospects. Enhancements have been made to our controls relating to electronic payments by or for us that we believe will reduce our risk of becoming a victim of future frauds related to our payments, including by wire transfers. However, cyber-related criminal activities continue to evolve and increase in sophistication, frequency and severity. As a result, the control enhancements that have been made, and any additional enhancements that may be made in the future, to our controls may not be successful in avoiding our becoming a victim to further cyber-related crimes.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions (including ransomware attacks) over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. No network or system can ever be completely secure, and the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in operations, reputation, or a material disruption of our development programs for an indeterminate period of time. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In some cases, data cannot be reproduced. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of the PoNS device or any future product candidate could be delayed. If a security breach results in the exposure or unauthorized disclosure of personal information, we could incur additional costs associated with data breach notification and remediation expenses, investigation costs, regulatory penalties and fines, and legal proceedings. Our insurance coverage may not be adequate to cover all the costs related to such breaches or attacks. In October 2019, we were the victim of a business email compromise, fraud which resulted in our incurring a loss of approximately $0.1 million.

Challenges to our tax positions in U.S. or non-U.S. jurisdictions, the interpretation and application of recent U.S. tax legislation or other changes in U.S. or non-U.S. taxation of our operations could harm our business, revenue and financial results.

We operate, or intend to operate, in a number of tax jurisdictions globally, including in the United States at the federal, state and local levels, and in several other countries, and we therefore are or will be subject to review and potential audit by tax authorities in these various jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and other tax liabilities, and tax authorities may disagree with tax positions we take and challenge our tax positions. Successful unilateral or multi-jurisdictional actions by various tax authorities may increase our worldwide effective tax rate, result in additional taxes or other costs or have other material consequences, which could harm our business, revenue and financial results.

Our effective tax rate may also change from year to year or vary materially from our expectations based on changes or uncertainties in the mix of activities and income allocated or earned among various jurisdictions,

changes in tax laws and the applicable tax rates in these jurisdictions (including future tax laws that may become material), tax treaties between countries, our eligibility for benefits under those tax treaties and the valuation of deferred tax assets and liabilities. Such changes could result in an increase in the effective tax rate applicable to all or a portion of our income, impose new limitations on deductions, credits or other tax benefits or make other changes that may adversely affect our business, cash flows or financial performance. For example, if we are unable to fully realize the benefit of interest expense incurred in future periods as a result of recent tax law changes (as discussed below), we may need to recognize a valuation allowance on any related deferred tax assets, which would impact our annual effective income tax rate.

In particular, on December 22, 2017, the Tax Cuts & Jobs Act, or TCJA, was signed into law. The legislation significantly changed U.S. tax law by, among other things, lowering the U.S. federal corporate income tax rate from 35% to 21%, implementing a modified territorial tax system and imposing a transition tax on deemed repatriated earnings of foreign subsidiaries, or the Section 965 Transition Tax. Certain changes established by the TCJA increased our effective tax rate in prior years, including a new income inclusion item for global intangible low-taxed income, or GILTI, and the Section 965 Transition Tax on our accumulated offshore earnings held in cash and illiquid assets. Additional changes have impacted the timing of our recognition of certain items of loss and deduction, including a new limitation on the company's deduction for business interest expense, a new limitation of the deduction for NOLs to 80% of current year taxable income, elimination of NOL carrybacks for NOLs arising after December 31, 2017 and the allowance of the indefinite carryforward of such NOLs, and increased bonus depreciation from 50% to 100% for certain qualified property.

Furthermore, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted on March 27, 2020 in response to the outbreak of COVID-19 and its consequences. The CARES Act introduced substantial changes to the U.S. tax code, the overall impact of which on our business is uncertain. For example, among other changes, the CARES Act increased the interest expense deductibility limitations and waived certain limitations on the use of NOLs, in each case, temporarily.

On July 23, 2020, final regulations were published that exempt certain income subject to a high rate of foreign tax from inclusion under GILTI for tax years beginning after December 31, 2017.

The cumulative impact of these and other changes in tax law is uncertain and our business and financial condition could be adversely affected. The impact of these changes on holders of our securities is also uncertain and could be adverse.

Risks Related to Our Common Stock

The reverse split of our common stock effected on December 31, 2020 could decrease our total market capitalization and has increased, and may continue to increase, the volatility of our stock price.

At a special meeting of our stockholders on December 28, 2020, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-5 to 1-for-35. Following such special meeting, our board of directors approved a 1-for-35 reverse split of our issued and outstanding shares of common stock. We filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on December 31, 2020, and our common stock began trading on a split-adjusted basis on The Nasdaq Capital Market on January 4, 2021.

There can be no assurance that the total market capitalization of our common stock after the reverse stock split will be equal to or greater than the total market capitalization before the reverse stock split or that the per share market price of our common stock following the reverse stock split will increase in proportion to the reduction in the number of shares of common stock outstanding before the reverse stock split. Furthermore, a decline in the market price of our common stock after the reverse stock split may result in a greater percentage decline than would occur in the absence of a reverse stock split, and the liquidity of our common stock could be adversely affected following such a reverse stock split.

The reverse stock split increased the Company's authorized but unissued shares of common stock, which could negatively impact a potential investor.

Because the number of authorized shares of the Company's common stock was not reduced proportionately, the reverse stock split increased the Board's ability to issue authorized and unissued shares without further stockholder action. The issuance of additional shares of common stock or securities convertible into common stock may have a dilutive effect on earnings per share and relative voting power and may cause a decline in the trading price of the common stock. The Company could use the shares that are available for future issuance in dilutive equity financing transactions, or to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management, including transactions that are favored by a majority of the stockholders or in which the stockholders might otherwise receive a premium for their shares over then-current market prices or benefit in some other manner.

We could be delisted from The Nasdaq Capital Market, which could seriously harm the liquidity of our stock and our ability to raise capital.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding maintaining a minimum share price, director independence and independent committee requirements, minimum stockholders' equity, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

On March 23, 2020, we received a Notice from the Staff of Nasdaq indicating that, based on the closing bid price of the common stock for the 30 consecutive business days preceding the Notice, we no longer meet Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Notice does not result in the immediate delisting of our common stock from The Nasdaq Capital Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days in which to regain compliance. In order to regain compliance with the Minimum Bid Price Requirement, the closing bid price of our common stock must be at least $1.00 for a minimum of ten consecutive business days.

On April 17, 2020, the Company the Second Notice for the Staff of Nasdaq stating that the 180-day period to regain compliance with the Minimum Bid Price Requirement has been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq has stated that compliance periods were suspended from April 16, 2020 until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period to regain compliance with the Minimum Bid Price Requirement. As a result of this extension, we were given to until December 3, 2020 to regain compliance with the Minimum Bid Price Requirement.

On December 4, 2020, the Company received notice from the Staff indicating that the Company was not eligible for an additional 180 day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that the Company's securities would be subject to delisting unless the Company timely requests a hearing before the Panel. The Company timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concludes and any extension granted by the Panel expires. On January 15, 2021, the Company received a notice from the Staff that the bid price deficiency of the Company had been cured, and that the Company was in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

However, there is no guarantee that we will remain compliant with the requirements of the Nasdaq Capital Market.

If we cease to be eligible to trade on The Nasdaq Capital Market:

- We may have to pursue trading in the United States on a less recognized or accepted market, such as the OTC Bulletin Board or the "pink sheets";

- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically;
- Our common stock may be deemed a "penny stock," and transactions in our common stock would be more difficult and cumbersome;
- We may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock; and
- The market price of the common stock may further decline.

A decline in the price of our common stock could affect our ability to raise any required working capital and adversely affect our operations.

A decline in the price of our common stock could result in a reduction in the liquidity of our common stock and a reduction in our ability to raise any required capital for our operations. Because our operations to date have been principally financed through the sale of equity securities, a decline in the price of our common stock could have an adverse effect upon our liquidity and our continued operations. A reduction in our ability to raise equity capital in the future may have a material adverse effect upon our business plans and operations. If our stock price declines, we may not be able to raise additional capital or generate funds from operations sufficient to meet our obligations.

An active trading market for our common stock on The Nasdaq Capital Market may not continue to develop or be sustained.

Although our common stock is listed on The Nasdaq Capital Market, we cannot assure you that an active trading market for our common stock will continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for investors in our common stock to sell their shares of our common stock without depressing the market price for the shares or to sell the shares at all.

Trading of our common stock could be sporadic, and the price of our common stock may be volatile; we caution you as to the highly illiquid nature of an investment in our shares.

Our common stock has been listed on the TSX since April 18, 2016 and on The Nasdaq Capital Market since April 11, 2018. Securities of microcap and small-cap companies have experienced substantial volatility in the past, often based on factors unrelated to the companies' financial performance or prospects. We believe that trading in our stock has been and will likely continue to be subject to significant volatility. These factors include macroeconomic developments in North America and globally and market perceptions of the attractiveness of particular industries. Factors unrelated to our performance that may affect the price of our common stock include the following: the extent of analytical coverage available to investors concerning our business may be limited if investment banks with research capabilities do not follow us, a reduction in trading volume and general market interest in our common stock may affect an investor's ability to trade significant numbers of shares of our common stock; the size of our public float may limit the ability of some institutions to invest in our common stock. As a result of any of these factors, the market price of our common stock at any given point in time may not accurately reflect our long-term value. The price of our common shares may increase or decrease in response to a number of events and factors, including: changes in financial estimates; our acquisitions and financings; quarterly variations in our operating results; the operating and share price performance of other companies that investors may deem comparable; and purchase or sale of blocks of our common stock. These factors, or any of them, may materially adversely affect the prices of our common shares regardless of our operating performance.

The market price of our common stock is affected by many other variables which are not directly related to our success and are, therefore, not within our control. These include other developments that affect the breadth of the public market for shares of our common stock and the attractiveness of alternative investments. The effect of these and other factors on the market price of our common stock is expected to make our common stock price volatile in the future, which may result in losses to investors.

We have not paid any dividends and do not foresee paying dividends in the future.

We intend to retain earnings, if any, to finance the growth and development of our business and do not intend to pay cash dividends on shares of our common stock in the foreseeable future. The payment of future cash dividends, if any, will be reviewed periodically by the board of directors and will depend upon, among other things, conditions then existing including earnings, financial condition and capital requirements, restrictions in financing agreements, business opportunities and other factors.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- stockholders are not entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders are not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders,

(iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Our certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. 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 such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery and federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. As a result of this decision, we do not currently intend to enforce the federal forum selection provision in our certificate of incorporation, unless the decision is reversed on appeal. However, if the decision is reviewed on appeal and ultimately overturned by the Delaware Supreme Court, we would enforce the federal district court exclusive forum provision.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

The United States Tax Cuts and Jobs Act of 2017 could adversely affect our business and financial condition.

The U.S. Tax Cuts and Jobs Act, or the TCJA, significantly reforms the Code. The TCJA, among other things, contains significant changes to U.S. federal corporate income taxation, including reduction of the U.S. federal corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks for net operating losses arising after December 31, 2017, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and creating, modifying or repealing many business deductions and credits. Federal net operating losses arising in taxable year ending after December 31, 2017 will be carried forward indefinitely pursuant to the TCJA. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse.

Risks Related to this Offering

Because our management will have broad discretion and flexibility in how the net proceeds from this offering are used, our management may use the net proceeds in ways with which you disagree or which may not prove effective.

We currently intend to use the net proceeds from this offering as discussed under "Use of Proceeds" in this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

If you purchase Units in this offering, you will incur immediate and substantial dilution in the net tangible book value of your shares.

The public offering price of the Units is substantially higher than the net tangible book value per share of our common stock. Investors purchasing Units in this offering will pay a price per share of common stock that will exceed the pro forma, as adjusted book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing Units in this offering will incur immediate dilution of $8.43 per share of common stock. As a result of the dilution to investors purchasing Units in this offering, investors will receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation of our company. The final public offering price was determined through negotiations between us and the underwriter in the offering. Furthermore, if the underwriter exercises its option to purchase additional shares of common stock and/or Warrants or our previously-issued options, warrants or other rights to acquire common stock at prices below the public offering price are exercised, you will experience further dilution. See "Dilution."

The Warrants are unlisted securities and there is no public market for them.

There is no established public trading market for the Warrants, and we do not expect a market to develop. In addition, the Warrants are not listed, and we do not intend to apply for listing of the Warrants on any securities exchange or trading system. Without an active market, the liquidity of the Warrants is limited, and investors may be unable to liquidate their investments in the Warrants.

The Warrants may not have any value.

The Warrants will be exercisable immediately upon issuance and will expire on the five year anniversary of the original issuance date at an initial exercise price of $16.302 per share. In the event that the price of a share of our common stock does not exceed the exercise price of the Warrants during the period when the Warrants are exercisable, the Warrants may not have any value.

The Warrants purchased in this offering do not entitle the holder to any rights as common stockholders until the holder exercises the Warrant for shares of our common stock.

Until you acquire shares of our common stock upon exercise of your Warrants purchased in this offering, such Warrants will not provide you any rights as a common stockholder, except as set forth in the Warrants. Upon exercise of your Warrants purchased in this offering, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

Purchasers in this offering may experience additional dilution of their investment in the future.

Subject to lock-up provisions described under "Underwriting", we are generally not restricted from issuing additional securities, including shares of common stock, securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or substantially similar securities. The issuance of securities may cause further dilution to our stockholders, including investors in this offering. In order to raise additional capital, such securities may be at prices that are not the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, including investors who purchase securities in this offering. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share in this offering. The exercise of outstanding stock options or warrants and the vesting of outstanding restricted stock units may also result in further dilution of your investment.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “may,” “will,” “should,” “could,” “anticipates,” “estimates,” “plans,” “projects,” “potential,” “continuing,” “ongoing,” “expects,” “believes,” “intends,” “targets,” “predicts,” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus, and in particular those factors included in the section entitled “Risk Factors.”

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should carefully read this prospectus and any related free writing prospectus and with the understanding that our actual future results may materially differ from what we expect.

Except as required by law, forward-looking statements speak only as of the date they are made, and we assume no obligation to update any forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the securities offered by this prospectus in this offering will be approximately $8.5 million (or $9.8 million if the underwriter fully exercises its overallotment option) after deducting commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering for funding operations, working capital and general corporate purposes. We may use a portion of the net proceeds for the acquisitions of businesses, products, technologies or licenses that are complementary to our business, although we have no present commitments or agreements to do so.

The allocation of the net proceeds of the offering represents our estimates based upon our current plans and assumptions regarding industry and general economic conditions, our future revenues and expenditures.

The amounts and timing of our actual expenditures may vary significantly and will depend on numerous factors, including market conditions, cash generated or used by our operations, business developments and opportunities that may arise and related rate of growth. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

Circumstances that may give rise to a change in the use of proceeds and the alternate purposes for which the proceeds may be used include:

- the existence of other opportunities or the need to take advantage of changes in timing of our existing activities;
- the need or desire on our part to accelerate, increase or eliminate existing initiatives due to, among other things, changing market conditions and competitive developments; and/or
- if strategic opportunities present themselves (including acquisitions, joint ventures, licensing and other similar transactions).

From time to time, we evaluate these factors and other factors and we anticipate continuing to make such evaluations to determine if the existing allocation of resources, including the proceeds of this offering, is being optimized. Pending the application of the net proceeds as described above, we will hold the net proceeds from this offering in short-term, interest-bearing, securities.

We believe that the net proceeds of this offering, together with cash on hand, will be sufficient to fund our operations throughout the third quarter of 2021, and we believe that we will need to raise additional capital to fund our operations thereafter. Additional capital may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we complete may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

MARKET INFORMATION AND DIVIDEND POLICY

Our common stock is listed on The Nasdaq Capital Market under the symbol "HSDT" and on the TSX under the symbol "HSM." See "Prospectus Summary—Recent Developments" in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market. The Warrants will not be traded on a national securities exchange.

On January 27, 2021, the last reported sale price of our common stock as reported on (a) The Nasdaq Capital Market was US $14.82 per share and (b) the TSX was CAD$18.53 per share.

On December 31, 2020, there were approximately 76 stockholders of record for our common stock. A substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

We have not historically paid cash dividends on our common stock. We intend to retain our future earnings, if any, to finance the expansion and growth of our business, and we do not expect to pay cash dividends on our capital stock in the foreseeable future. Payment of future cash dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with any debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay any dividends in the future, there can be no assurance that we will continue to pay such dividends.

Our transfer agent is American Stock Transfer & Trust Company LLC, 6201 15th Avenue, Brooklyn, New York 11219; Telephone: 800-937-5449.

CAPITALIZATION

The following table sets forth our cash and our capitalization as of September 30, 2020, as follows:

- on an actual basis;
- on a pro forma basis, to give effect to our issuance and sale of 187,646 shares of common stock and warrants to purchase an aggregate of 93,817 shares of common stock, for an aggregate purchase price of approximately $3.4 million in the October 2020 Private Placement; and
- on a pro forma, as adjusted basis, to give effect to the pro forma adjustment above, and to further give effect to the sale of the securities offered hereby at a public offering price of $14.82 per Unit and the use of proceeds, as described in the section entitled "Use of Proceeds", assuming no exercise by the underwriter of its overallotment option.

You should read this information in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this prospectus. The information provided herein has been adjusted to reflect our 1-for-35 reverse stock split that was affected after trading on December 31, 2020.

	As of September 30, 2020 (in thousands, except share and per share data)		
	Actual	Pro Forma	Pro Forma, As Adjusted
Cash	$ 2,680	$ 5,924	$ 14,406
Stockholders' equity:			
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2020	—	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 1,295,805, 1,483,451 and 2,131,223 shares, respectively, issued and outstanding as of September 30, 2020	1	1	2
Additional paid-in capital	120,257	123,501	131,982
Accumulated other comprehensive loss	(693)	(693)	(693)
Accumulated deficit	(116,368)	(116,368)	(116,368)
Total stockholders' equity	**$ 3,197**	**$ 6,441**	**$ 14,923**

The above discussion and table are based 1,295,805 shares of common stock outstanding as of September 30, 2020 and excludes the shares of common stock issuable upon exercise of the Warrants being offered by this prospectus and also excludes the following as of that date:

- 112,224 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2020, at a weighted-average exercise price of $194.68 per share;
- 197,232 shares of common stock issuable upon the exercise of warrants (excluding the Warrants) outstanding as of September 30, 2020, at a weighted-average exercise price of US$54.71, and 68,351 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2020, at a weighted-average exercise price of CAD$428.75 (or US$335.28 based on the exchange rate on January 11, 2021);
- 96,798 shares of common stock reserved for future issuance under our 2018 Omnibus Incentive Plan as of September 30, 2020;
- an aggregate of 164 shares of fully-vested restricted stock units granted prior to September 30, 2020;
- 94,778 shares of common stock issuable upon the exercise of warrants (excluding the Warrants) issued subsequent to September 30, 2020, at a weighted average exercise price of US$15.92;

- 965 restricted stock units issued subsequent to September 30, 2020; and
- 82,762 shares issued upon the settlement of restricted stock units and the exercise of warrants subsequent to September 30, 2020.

All share and per share amounts for all periods presented in this prospectus and the registration statement of which it forms a part have been retroactively adjusted for the reverse stock split effected on December 31, 2020.

DILUTION

A purchaser of our securities in this offering will be diluted to the extent of the difference between the price you may for each share of our common stock and the net tangible book value per share of our common stock after this offering. Net tangible book value per share prior to this offering is equal to our total tangible assets minus total liabilities, all divided by 1,295,805 shares of common stock outstanding at September 30, 2020. Our historical net tangible book value as of September 30, 2020 was approximately $1.9 million, or $1.46 per share of our common stock. As of September 30, 2020, our pro forma net tangible book value was $5.1 million, or $3.46 per share, after giving effect to the October 2020 Private Placement. The information provided in this section has been adjusted to reflect the 1-for-35 reverse stock split that was effected after trading December 31, 2020.

After giving effect to our sale in this offering of 647,772 Units, at a public offering price of $14.82 per Unit, excluding shares that may be issued upon exercise of the underwriters' overallotment option and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2020 would have been approximately $13.6 million, or $6.39 per share of our common stock. This amount represents an immediate increase of net tangible book value to our existing stockholders of $2.93 per share and an immediate dilution of $8.43 per share to the new investors purchasing securities in this offering. The following table illustrates the dilution in net tangible book value per share to new investors:

Public offering price per Unit		$14.82
Historical net tangible book value per share at September 30, 2020	$1.46	
Pro forma increase in net tangible book value per share attributable to the October 2020 Private Placement	$2.00	
Pro forma net tangible book value per share at September 30, 2020	$3.46	
Increase per share attributable to investors purchasing securities in this offering	$2.93	
Pro forma, as adjusted net tangible book value per share, after this offering		$ 6.39
Dilution per share to investors participating in this offering		$ 8.43

The above discussion and table are based 1,295,805 shares of common stock outstanding as of September 30, 2020 and excludes the shares of common stock issuable upon exercise of the Warrants being offered by this prospectus and also excludes the following as of that date:

- 112,224 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2020, at a weighted-average exercise price of $194.68 per share;
- 197,232 shares of common stock issuable upon the exercise of warrants (excluding the Warrants) outstanding as of September 30, 2020, at a weighted-average exercise price of US$54.71, and 68,351 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2020, at a weighted-average exercise price of CAD$428.75 (or US$335.28 based on the exchange rate on January 11, 2021);
- 96,798 shares of common stock reserved for future issuance under our 2018 Omnibus Incentive Plan as of September 30, 2020;
- an aggregate 164 shares of fully-vested restricted stock units granted prior to September 30, 2020.
- 94,778 shares of common stock issuable upon the exercise of warrants (excluding the Warrants) issued subsequent to September 30, 2020, at a weighted average exercise price of US$15.92;
- 965 restricted stock units issued subsequent to September 30, 2020; and
- 82,762 shares issued upon the settlement of restricted stock units and the exercise of warrants subsequent to September 30, 2020.

To the extent that outstanding options or warrants are converted or exercised, you could experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of additional equity, the issuance of these shares could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our interim unaudited condensed consolidated financial statements and related notes and our audited consolidated financial statements and related notes included elsewhere in this prospectus. All financial information is stated in U.S. dollars unless otherwise specified.

Overview

We are a neurotechnology company focused on neurological wellness. Our purpose is to develop, license or acquire non-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

Our first product, known as the PoNS™ device, is authorized for sale in Canada as a class II, non-implantable medical device intended as a short term treatment (14 weeks) of gait deficit due to symptoms from multiple sclerosis (MS) and balance deficit due to mild-to-moderate traumatic brain injury (mmTBI) and is to be used in conjunction with physical therapy ("PoNS Treatment"). It is an investigational medical device in the United States, the European Union (EU), and Australia (AUS). The device is currently under review for de novo classification and clearance by the U.S. Food and Drug Administration (the FDA) as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment is not currently commercially available in the United States, the European Union or Australia.

Regulatory Status Worldwide

Canadian Regulatory Status: mmTBI and MS

On October 17, 2018, we received our Canadian marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for use as a short-term treatment (14 weeks) of balance deficit due to mmTBI.

On March 18, 2020, we received marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for the treatment of gait deficit in patients with mild and moderate MS symptoms, when used in conjunction with physical therapy. Our market authorization application comprised objective statistical evidence as well as independently reviewed clinical research analysis. We believe this label expansion will significantly expand our addressable market opportunity in Canada to include a patient population that is motivated to pursue treatment options which may resolve or delay the progression of MS gait deficit symptoms.

US Regulatory Status: MS

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. We believe the existing published data and real-world evidence with use of the PoNS for the treatment of gait disorder in patients with mild and moderate MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo classification and clearance to enable US marketability. Novel treatments for MS are highlighted as a specific target of the FDA as a high unmet medical need disease.

On May 7, 2020 we received Breakthrough Designation for the PoNS device as a potential treatment for gait deficit due to symptoms of Multiple Sclerosis ("MS"), to be used as an adjunct to a supervised therapeutic exercise program. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and de novo classification and clearance, consistent with FDA's mission to protect and promote public health.

The Breakthrough Devices Program replaces the Expedited Access Pathway and Priority Review for medical devices. The FDA considers devices granted designation under the Expedited Access Pathway to be part of the Breakthrough Devices Program.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

Breakthrough Device Designation does not change the requirements for approval of an application for a marketing authorization under section 510(k) of the Food, Drug, and Cosmetic Act.

On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to the Company's request for de novo classification and clearance of the PoNS device. During the substantive review phase of a request for de novo classification and clearance, FDA may request additional information in order to obtain information necessary for the FDA to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted. The FDA's request for additional information was received approximately 75 days from the submission date, which is consistent with FDA's expected timing for review of a Breakthrough Designated product, such as the PoNS device. The FDA's request for additional information includes requests for additional analysis of clinical data and proposes certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

US Regulatory Status: mmTBI

Our U.S. regulatory strategy initially focused on pursuing de novo classification and clearance of the PoNS device from the FDA for the treatment of balance deficit due to mmTBI.

We submitted a request for de novo classification and clearance of the PoNS device to the FDA for this indication in August 2018. This request was supported by data from two of our clinical trials in mmTBI, including our registrational trial, TBI-001.

In April 2019, we announced the FDA had completed its review and had denied our request for de novo classification and clearance of the PoNS device for the treatment of balance deficit due to mmTBI. In reaching its conclusion, the FDA noted, via a denial letter, that although the safety profile of the PoNS device is acceptable, the FDA did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy on the improvements from baseline. The FDA noted that we could generate additional data to address its concerns and resubmit our application.

In October 2019, we had a pre-submission meeting where the FDA provided feedback needed to help complete the design of a new clinical trial intended to address the FDA's request for a trial that demonstrates the benefit of the PoNS Treatment compared to physical therapy alone. In January 2020, we received the FDA's feedback on the minutes from the October 2019 pre-submission meeting. In its feedback, the FDA provided post-meeting notes with specific recommendations regarding the trial design that were not discussed in the October 2019 pre-submission meeting.

Based on the receipt of the FDA's final minutes from the pre-submission meeting, we finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. TBI-002 will be a multi-center, randomized trial in the U.S. and Canada consisting of 103 subjects

with balance deficit due to mmTBI. Although TBI-002 will take longer and be more costly than the design that we had discussed at our October 2019 pre-submission meeting, we believe that the chances of obtaining FDA de novo classification and clearance will be significantly increased if we incorporate the FDA's pre-submission feedback into this next trial design.

TBI-002 will proceed in two phases: a run-in phase, followed by a treatment phase. During the run-in phase, all subjects will receive 5 weeks of physical therapy alone. Subjects will then be randomized and assigned to one of two groups in the treatment phase where subjects will either receive up to 10 weeks of physical therapy with the PoNS device or 10 weeks of physical therapy without the PoNS device. The primary effectiveness endpoint of TBI-002 will be a responder analysis.

Prior to the COVID-19 pandemic, our expectation was that we would move forward with the revised protocol and estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

European Regulatory Status

In December 2018, we submitted an application for a CE Mark, which, if approved, would allow us to market the PoNS device in the EU. During the second quarter of 2019, we engaged with regulators in Europe to answer questions that we received from them as part of their review of our PoNS device for CE marking. In August 2019, we withdrew our application from the EU marketing process due to uncertainty in Europe caused by the switch from the Medical Device Directive, or MDD, to the Medical Device Regulation, or MDR, Brexit, and the withdrawal of Lloyd's Register Quality Assurance, our notified body, from the EU notified body business. We have engaged G-MED NA (North America) as our new ISO registrar and new notified body and will reconsider submitting to the EU when conditions stabilize.

Australian Regulatory Status

In the third quarter of 2019 we initiated the submission of our application to the Therapeutic Goods Administration, or TGA. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. We are currently awaiting additional feedback from TGA on our application.

Commercialization

Share Purchase Agreement and Co-Promotion Agreement

During the third quarter of 2019, we engaged with HTC through the joint steering committee in discussions regarding the future development of the commercialization of the PoNS device and PoNS Treatment in Canada. As we worked with Heuro to expand the commercial infrastructure, the complexity and feasibility of using a franchise model to build a market for PoNS including the physical therapy component became challenging. By acquiring Heuro, as noted below, we were able to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

On October 30, 2019, we and HTC entered into a Share Purchase Agreement, or the SPA, whereby we, through our wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately $1.6 million was paid to HTC, which included (1) the repayment to HTC for their investment in the set-up of Heuro's initial commercial infrastructure including, the establishment of five authorized PoNS clinics across Canada, (2) the current market value of 55 PoNS devices which we also provided to HTC under the SPA, (3) the CAD$750,000 receivable from the September 2018 strategic alliance agreement and (4) the sale of exclusivity rights granted to HTC in the Co-Promotion Agreement, as defined below, to provide PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia.

In connection with the Share Purchase Agreement, on October 30, 2019, we entered into a Clinical Research and Co-Promotion Agreement with HTC, or the Co-Promotion Agreement, whereby each company will promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. The co-promotion arrangement terminated on December 31, 2020. Also, subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS-authorized clinic since February 2019. HTC will purchase the PoNS devices for use in these regions exclusively from us and on terms no less favorable than the then-current standard terms and conditions. This exclusivity right has an initial term of ten years, renewable by HTC for one additional ten year term upon sixty days' written notice to us.

Canada Commercialization Efforts

From a real-world results perspective, in Canada thus far, the collective experience of our patients that have completed the 14-week PoNS Treatment have been encouraging. Consistent with what we saw in our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial TBI patients are demonstrating improvements in balance and gait within the first two weeks followed by continued improvement over the following twelve weeks. The majority of patients have a mean patient adherence to treatment of over 90% and showed significant improvement in their balance and gait with a meaningful clinical difference at the end of their treatment. The consistency of the patient results from our initial commercial experience supports our plans to expand access PoNS Treatment in Canada.

March 2019 marked the commercialization of our PoNS Treatment in Canada, where PoNS became the first and only device authorized by Health Canada for the treatment of balance deficit due to mmTBI. Throughout 2019 we made important progress in advancing and refining our commercialization strategy in Canada building access, awareness and credibility for the PoNS Treatment. These efforts, which were led by our local Canadian commercial team, included the establishment of our authorized clinic network throughout Canada, launching digital marketing campaigns, and building key opinion leader and advocacy networks.

During the third quarter of 2019, we made the strategic decision to change our business model in Canada in order to accelerate the adoption of our novel technology. On October 30, 2019, we acquired the Heuro Canada operating entity from HTC which allowed us to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

On March 18, 2020, the Company received notification that its Canadian Class II license amendment application for the treatment of gait deficit in patients with symptoms from MS, when used in conjunction with physical therapy, was successful and received marketing authorization for PoNS from Health Canada.

Following in-depth market analysis and field intelligence, our Canadian commercial team began an expansion plan to increase the number of authorized PoNS clinics. In the first two months of 2020, we authorized 7 new clinic locations for a total of 14 clinic locations to provide PoNS Treatment across Canada. As of June 30, 2020, we had 20 clinic locations which we increased to 22 clinic locations as of September 30, 2020 and to 31 clinic locations as of December 31, 2020. There is a conscious shift in focus to driving patient throughput to these 31 clinics as we head into 2021. Sales performance in Canada continues to be impacted by the COVID-19 pandemic due to the space restrictions that the provincial governments have imposed as well as the risk tolerance of patients and therapists.

In collaboration with Toronto Rehabilitation Institute (part of University Health Network) we are continuing our clinical experience program, the results of which we will look to publish in 2021.

We continue to refine our go-to-market pricing model based on market feedback. Our modified pricing approach is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment. We have also experimented with various promotional pricing programs resulting in lower unit prices

for both PoNS system purchases and mouthpieces in order to increase access to the PoNS treatment and drive market awareness which we expect to result in an increase in the volume of units sold, which was seen in the second half of 2020 when compared to the second half of 2019. We intend to keep the promotional pricing in place at least through the first quarter of 2021.

The value dossiers for mmTBI and MS that were created in mid-2020 to fully demonstrate in both scientific and financial terms, the merits of PoNS Treatment for claimants are now being implemented along with submissions from clinics on behalf of their patients. The dossier is provided to our clinics across Canada to submit as part of treatment plans with reimbursement applications to the payer community. Our reimbursement strategy for mmTBI continues to focus on the auto collision insurance and workers' compensation market as well as long-term disability cases. Our reimbursement strategy for MS is focused on commercial insurers/extended health benefits. Moreover, we are currently considering the development of the PoNS device for other potential indications, including stroke as well as label expansion for our existing indications.

As part of our overall PoNS Treatment strategy, we are also gathering comprehensive health economic assessments of treatment outcomes. These data will, in-turn, be used to support our applications for workers compensation, auto insurance and commercial insurance reimbursement initiatives in Canada, the United States and other markets around the world. The Canadian commercial experience will be extremely valuable to prepare us for our launches in the United States and internationally.

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS-authorized clinic locations across Canada from March until June 2020. Patients who completed their initial training in the clinics prior to the closures have been able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, they are all currently operating at reduced capacity within provincial guidelines, which limited operations to 50% capacity during the second half of 2020. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 has led to further restrictions on clinic activities.

Additionally, while we do not currently have any clinical trials underway, we are running clinical experience programs in Canada and have experienced delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff, leading to further delays in the development and approval of the Company's product candidate. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

The COVID-19 pandemic and other outbreaks may cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device, and in the second quarter of 2020, two of our business

partners diverted resources towards other activities related to COVID-19, resulting in delays in the development and manufacturing of our product. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The extent to which the COVID-19 pandemic will continue to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. We do not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

October 2020 Private Placement

On October 26, 2020, the Company closed the October 2020 Private Placement of an aggregate of 187,646 shares of common stock and warrants to purchase an aggregate of 93,817 shares of common stock at a purchase price of $18.20 per unit, consisting of one share and a warrant to purchase 0.50 shares of common stock, resulting in gross proceeds of approximately $3.4 million, excluding the proceeds, if any, that the Company may receive in the future from the exercise of the warrants. The Company incurred $0.2 million in share issuance costs, including placement agent fees. The warrants have an initial exercise price of $15.82 per share and are exercisable for a period of three years from the date of issuance. The Company also issued warrants to the placement agent to purchase 961 shares of common stock, with an exercise price of $19.775 per share. An officer of the Company and affiliates of an officer and director of the Company participated in the private placement on the same terms and conditions as all other purchasers, except that they paid $18.354 per unit and their warrants have an exercise price of $16.1665 per share.

Pursuant to the securities purchase agreement for the October 2020 Private Placement, if we issue any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the private placement, each purchaser who subscribed for at least $250,000 in the private placement has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

Nasdaq Delisting

On March 23, 2020, we received a Notice from the Staff of Nasdaq indicating that, based on the closing bid price of the common stock for the 30 consecutive business days preceding the Notice, we no longer meet the Minimum Bid Price Requirement. The Notice does not result in the immediate delisting of our common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days in which to regain compliance. In order to regain compliance with the Minimum Bid Price Requirement, the closing bid price of our common stock must be at least $1.00 for a minimum of ten consecutive business days.

On April 17, 2020, the Company the Second Notice for the Staff of Nasdaq stating that the 180-day period to regain compliance with the Minimum Bid Price Requirement has been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq stated that compliance periods were suspended from April 16, 2020 until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period to regain compliance with the Minimum Bid Price Requirement. As a result of this extension, we were given to until December 3, 2020 to regain compliance with the Minimum Bid Price Requirement.

On December 4, 2020, the Company received notice from the Staff indicating that the Company was not eligible for an additional 180 day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that the Company's securities would be subject to delisting unless the Company timely requests a hearing before the Panel. The Company timely submitted a request for a hearing before the Panel, which request

stayed any suspension or delisting action by Nasdaq at least until the hearing process concludes and any extension granted by the Panel expires. On January 15, 2021, the Company received notice from the Staff that the bid price deficiency of the Company had been cured, and that the Company was in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

Reverse Stock Split

At a special meeting of our stockholders on December 28, 2020, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-5 to 1-for-35 to be determined at the discretion of our Board of Directors, whereby each outstanding 5 to 35 shares would be combined, converted and changed into 1 share of our common stock, to enable the Company to comply with Nasdaq's continued listing requirements. Following such meeting, our board of directors approved a final reverse stock split ratio of 1-for-35. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts for all periods presented in this prospectus and the registration statement of which it forms a part have been retroactively adjusted to reflect the reverse stock split we previously effected on January 22, 2018 and for the reverse stock split effected on December 31, 2020.

Results of Operations

Nine Months Ended September 30, 2020 compared to the Nine Months Ended September 30, 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019 (amounts in thousands):

	Nine Months Ended September 30,		
	2020	2019	Change
Revenue:			
Product sales, net	$ 441	$ 1,295	$ (854)
Fee revenue	9	49	(40)
License revenue	20	—	20
Total operating revenue	**470**	**1,344**	**(874)**
Cost of sales:			
Cost of product sales	187	538	(351)
Gross profit	**283**	**806**	**(523)**
Operating expenses:			
Research and development	3,755	6,462	(2,707)
Selling, general and administrative	7,625	12,715	(5,090)
Amortization expense	287	—	287
Total operating expenses	**11,667**	**19,177**	**(7,510)**
Operating loss	**(11,384)**	**(18,371)**	**6,987**
Other (expense) income:			
Other income	63	35	28
Change in fair value of derivative financial instruments	4	14,033	(14,029)
Foreign exchange loss	(278)	(147)	(131)
Total other (expense) income	(211)	13,921	(14,132)
Net loss	**$(11,595)**	**$ (4,450)**	**$ (7,145)**

Revenue

For the nine months ended September 30, 2020, we recognized revenue of $0.5 million, of which $0.4 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada, $9 thousand was generated from fee revenue related to engaging new PoNS-authorized clinics, and $20 thousand was generated from license fee revenue related to our Co-Promotion Agreement with HTC. For the nine months ended September 30, 2019, we recognized revenue of $1.3 million, of which $1.3 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada and $49 thousand was generated from fee revenue related to engaging new PoNS-authorized clinics. The decrease year-over-year in revenue generated through product sales of our PoNS device in Canada is primarily due to pent up demand positively impacting our product sales for the first six months of 2019, the COVID-19 pandemic negatively impacting our product sales beginning in March 2020 and, to a lesser extent, the impact of price changes, focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment, that we began implementing in September 2019.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, royalty expense, freight charges, customs duties as well as wages and salaries of employees involved in the management of the supply chain and

logistics of fulfilling our sales orders. For the nine months ended September 30, 2020, we incurred $0.2 million in our cost of sales. For the nine months ended September 30, 2019, we incurred $0.5 million in our cost of sales, which also included certain support services provided by Heuro on our behalf.

Research and Development Expense

Research and development, or R&D, expenses were $3.8 million for the nine months ended September 30, 2020 compared to $6.5 million for the nine months ended September 30, 2019, a decrease of $2.7 million. The decrease was attributable to a $0.9 million reduction in product development costs due to completion of the PoNS device development in 2019 and a $0.5 million reduction in wages and salaries. Medical affairs expenses also decreased by $1.0 million due to the effort in 2019 to create awareness of the PoNS device by delivery of clinical and scientific data to key opinion leaders, professional societies and practitioners. There was also a reduction of $0.3 million in professional services expenses.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expenses were $7.6 million for the nine months ended September 30, 2020 compared to $12.7 million for the nine months ended September 30, 2019, a decrease of approximately $5.1 million. The decrease was primarily due to $1.7 million in less wages and salaries due to higher headcount in 2019 and a $1.9 million reduction in commercial operations expense as in 2019 we invested in marketing and distribution capabilities in support of our US launch prior to receiving denial for clearance from the FDA. Stock-based compensation expense also decreased by $1.4 million and legal expenses decreased by $0.5 million. These decreases were partially offset by a $0.2 million impairment loss related to intangible assets in 2020 and a $0.1 million loss as the result of the disposal of property and equipment.

Amortization Expense

Amortization expense consists of the periodic amortization of intangible assets, including customer relationships, proprietary software and reacquired rights recognized in connection with the acquisition of Heuro on October 30, 2019 and internally developed software. For the nine months ended September 30, 2020, amortization expense was $0.3 million. No amortization expense was recorded during the nine months ended September 30, 2019.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of $4 thousand for the nine months ended September 30, 2020 compared to a gain of $14.0 million for the nine months ended September 30, 2019.

The change in fair value of our derivative financial instruments was primarily attributable to the change in our stock price, volatility and the number of derivative financial instruments being measured during the period. The change in the fair value of derivative financial instruments is a non-cash item.

Foreign Exchange Loss

Foreign exchange loss was $0.3 million for the nine months ended September 30, 2020, compared to a loss of $0.1 million for the nine months ended September 30, 2019. This was primarily due to fluctuations in the foreign exchange rate as it relates to the amount of Canadian dollars held at the end of each reporting period.

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018 (amounts in thousands):

	Year Ended December 31,		
	2019	2018	Change
Revenue:			
Product sales, net	$ 1,454	$ —	$ 1,454
Fee revenue	37	—	37
License revenue	5	478	(473)
Total operating revenue	**1,496**	**478**	**1,018**
Cost of sales:			
Cost of product sales	846	—	846
Gross profit	**650**	**478**	**172**
Operating expenses:			
Research and development	8,061	9,939	(1,878)
Selling, general and administrative	16,521	17,214	(693)
Amortization expense	64	—	64
Total operating expenses	**24,646**	**27,153**	**(2,507)**
Operating loss	(23,996)	(26,675)	2,679
Other income (expense):			
Other income	95	63	32
Change in fair value of derivative financial instruments	14,113	(3,577)	17,690
Foreign exchange gain	7	1,566	(1,559)
Total other income (expense)	14,215	(1,948)	16,163
Net loss	**$ (9,781)**	**$ (28,623)**	**$18,842**

Revenue

For the year ended December 31, 2019, we recognized revenue of $1.5 million, of which $1.46 million was generated through product sales of our PoNS device in Canada pursuant to our executed supply agreements with neuroplasticity clinics in Canada, $37 thousand was generated in fee revenue from franchise agreements Heuro executed with neuroplasticity clinics engaging in providing the PoNS Treatment and $5 thousand was generated from license fee revenue related to or co-promotion agreement with HTC. For the year ended December 31, 2018, we recognized license fee revenue of $0.5 million under an exclusive strategic alliance agreement.

Cost of Sales

For the year ended December 31, 2019, we incurred $0.8 million in our costs of sales. This included the costs to manufacture the PoNS device, royalty expense, freight charges, customs duties as well as wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling our sales orders. Prior to the completion of the Heuro acquisition on October 30, 2019, it also included certain support services provided by Heuro on our behalf. We had no cost of sales for the year ended December 31, 2018.

Research and Development Expenses

Research and development, or R&D, expenses were $8.1 million for the year ended December 31, 2019, compared to $9.9 million for the year ended December 31, 2018, a decrease of approximately $1.9 million. The decrease was primarily driven by a $3.3 million reduction in product development costs due to the completion of

the PoNS device development and transfer to the scale manufacturer and a $0.4 million decrease in regulatory consulting expenses as that work was performed in-house during 2019. These decreases were partially offset by a $1.1 million increase in medical affairs expenses related to our medical science liaison's efforts in the delivery of our clinical and scientific data and clinical education to key opinion leaders, professional societies and practitioners to help enhance our PoNS Treatment at home and in the clinic as well as feedback that can be incorporated in our PoNS device and training materials. Wages and salaries also increased by $0.9 million due to increased regulatory and quality management headcount to support our Canadian launch.

General and Administrative Expenses

General and administrative, or G&A, expenses were $16.5 million for the year ended December 31, 2019, compared to $17.2 million for the year ended December 31, 2018, a decrease of $0.7 million. The decrease was primarily due to lower stock-based compensation expense of $3.4 million, which was mainly the result of the change in our functional currency. During the second quarter of 2018, all of our outstanding stock options were revalued due to the liability classification of our stock options as a result of a change in our functional currency in April 2018 as the exercise price of our stock options were denominated in a currency other than our functional currency. Consulting fees decreased $1.0 million. These decreases were partially offset by higher commercial operations expenses of $1.8 million as we invested in reimbursement, marketing and distribution capabilities in support of our US launch prior to receiving denial for clearance from the FDA, as well as an increase in wages and salaries of $0.9 million to support our commercial launch, and an additional increase of $0.6 million in severance expense. Bad debt expense increased $0.2 million due to customer collectability exposure associated with us generating product sales for the first time in 2019.

Change in Fair Value of Derivative Financial Instruments

The change in fair value of derivative financial instruments was a gain of $14.1 million for the year ended December 31, 2019, compared to a loss of $3.6 million for the year ended December 31, 2018.

The change in fair value of derivative financial instruments was primarily attributable a change in our stock price, volatility and the number of derivative financial instruments being measured during the period (see Note 3 to our audited consolidated financial statements included elsewhere in this prospectus). The change in the fair value of derivative financial instruments is a non-cash item.

Foreign Exchange Gain (Loss)

Foreign exchange gain was $7 thousand for the year ended December 31, 2019, compared to a gain of $1.6 million for the year ended December 31, 2018. This was primarily due to fluctuations in the foreign exchange rate as it relates to the amount of Canadian dollars held at the end of each reporting period.

Statement of Cash Flows

Nine Months Ended September 30, 2020 Compared to Nine Months Ended September 30, 2019

The following table summarizes our cash flows for the nine months ended September 30, 2020 and 2019 (amounts in thousands):

	Nine Months Ended September 30,		
	2020	2019	Change
Net cash used in operating activities	$(9,567)	$(16,460)	$ 6,893
Net cash provided by (used in) investing activities	40	(260)	300
Net cash provided by financing activities	6,727	163	6,564
Effect of exchange rate changes on cash	21	(7)	28
Net decrease in cash	$(2,779)	$(16,564)	$13,785

Net Cash Used in Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2020 was $9.6 million. This was comprised of a loss from operations of $11.6 million and $1.0 million net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items of $3.0 million comprised mainly of stock-based compensation of $2.0 million, unrealized foreign exchange losses of $0.2 million, depreciation and amortization of $0.4 million, impairment loss on intangible assets of $0.2 million, provision for doubtful accounts of $0.2 million, loss on disposal of office furniture of $0.1 million and gain on lease modification of $0.1 million.

Net cash used in operating activities during the nine months ended September 30, 2019 was $16.5 million. This was comprised of a loss from operations of $18.4 million and $1.6 million net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items comprised of stock-based compensation of $3.3 million and unrealized foreign exchange losses of $0.2 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2020 was $40 thousand, which was primarily related to the sale of office furniture, offset partially by the purchase of equipment.

Net cash used in investing activities during the nine months ended September 30, 2019 was $0.3 million, which was primarily related to the purchase of computer software, furniture and fixtures for our office.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2020 was $6.7 million, which consisted of proceeds from the issuance of common stock from the 2020 ATM and March 2020 Offering, net of share issuance costs.

Net cash provided by financing activities during the nine months ended September 30, 2019 was $0.2 million, which consisted primarily of proceeds from the exercise of our April 2016 warrants.

Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

The following table summarizes our cash flows for the years ended December 31, 2019 and 2018 (amounts in thousands):

	Year Ended December 31,		
	2019	2018	Change
Net cash used in operating activities	$ (20,999)	$ (19,621)	$ (1,378)
Net cash used in investing activities	(769)	(440)	(329)
Net cash provided by financing activities	1,653	40,028	(38,375)
Effect of foreign exchange rate changes on cash	(9)	54	(63)
Net (decrease) increase in cash	$ (20,124)	$ 20,021	$(40,145)

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was $21.0 million. This was comprised of a net loss of $9.8 million, the change in the fair value of our derivative liabilities of $14.1 million and $2.2 million net cash used resulting from changes in operating assets and liabilities, partially offset by certain adjustments for non-cash items comprised of stock-based compensation expense of $4.7 million, depreciation and amortization of $0.2 million, bad debt expense of $0.2 million and unrealized foreign exchange loss of $0.1 million.

Net cash used in operating activities for the year ended December 31, 2018 was $19.6 million. This was comprised of a net loss of $28.6 million, adjusted for non-cash items including the change in the fair value of our derivative liabilities of $3.6 million, stock-based compensation expense of $8.1 million, which amounts were partially offset by unrealized foreign exchange gain of $1.7 million and changes in operating assets and liabilities of $1.0 million.

Net Cash used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2019 was $0.8 million, which was primarily comprised of $0.4 million for the acquisition of Heuro, and $0.3 million for property and equipment consisting of $0.1 million for computer equipment, $0.1 million for furniture and fixtures at our headquarters location and $0.1 million for equipment that will be used in the commercial production of the PoNS device. Net cash used in investing activities for the year ended December 31, 2018 was $0.4 million, which was primarily comprised of $0.2 million for furniture and fixtures at our headquarters location and a $0.2 million laser marking equipment that will be used in the commercial production of the PoNS device.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2019 was $1.7 million, which was primarily comprised of $1.7 million in gross proceeds received from the November 2019 public offering from the sale of 137,571 shares of our common stock and $0.2 million in proceeds from the exercise of stock options and warrants. These proceeds were partially offset by $0.2 million in issuance costs primarily related to our public offering.

Net cash provided by financing activities for the year ended December 31, 2018 was $40.0 million, which was primarily comprised of $38.5 million received from offerings of our common stock and warrants. In April 2018, we received approximately $18.4 million in gross proceeds from a public offering from the sale of 70,376 shares of our common stock and accompanying warrants. In November 2018, we received approximately $20.1 million in a public offering from the sale of 69,696 shares of our common stock. For the year ended December 31, 2018, we also received approximately $4.7 million in proceeds from the exercise of stock options and warrants. These proceeds were partially offset by $3.2 million in issuance costs primarily related to our public offering.

Liquidity and Capital Resources

Our consolidated financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation. Our major sources of cash have been proceeds from various public and private offerings of our common stock and exercises of stock options and warrants. From June 2014 through September 30, 2020, we raised approximately $103.2 million in gross proceeds from various public and private offerings of our common stock as well as the exercise of stock options and warrants. As described below, on October 26, 2020, we closed the October 2020 Private Placement of shares of common stock and warrants for total gross proceeds of approximately $3.4 million.

The following table summarizes our cash and working capital (which we define as current assets less current liabilities excluding derivative financial instruments) as of September 30, 2020 and December 31, 2019 (amounts in thousands):

	September 30, 2020	December 31, 2019
Cash	$ 2,680	$ 5,459
Working capital	$ 1,571	$ 3,444

We currently have limited working capital and liquid assets. Our cash as of September 30, 2020 was approximately $2.7 million. As noted above, subsequent to the date of our latest balance sheet, on October 26, 2020, we closed the October 2020 Private Placement of an aggregate of 187,646 shares of common stock and warrants to purchase an aggregate of 93,817 shares of common stock at purchase price of $18.20 per unit ($18.354 per unit for certain participating affiliates), consisting of one share and a warrant to purchase 0.50 shares of common stock, resulting in net proceeds of approximately $3.2 million after deducting placement agents fees and estimated expenses and excluding the proceeds, if any, that we may receive in the future from the exercise of the warrants. The warrants have an initial exercise price of $15.82 per share ($16.1665 per share for certain participating affiliates) and are exercisable for three years from the date of issuance. The Company also issued warrants to the placement agent to purchase 961 shares of common stock, with an exercise price of $19.775 per share.

Pursuant to the securities purchase agreement for the October 2020 Private Placement, if we issue any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the private placement, each purchaser who subscribed for at least $250,000 in the private placement has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

While we have started generating revenue from the commercial sale of our PoNS device in Canada, we expect to incur significant losses until such time as our revenue exceeds our expenses and during this time, we will require additional funding to fund our ongoing activities. We believe that our existing capital resources, including the net proceeds from the October 2020 Private Placement, will be sufficient to fund our operations throughout most of the first quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect our expenses to increase over time in connection with our ongoing activities, particularly if and as we: invest in marketing and distribution capabilities in support of potentially commercializing our PoNS device in the U.S., if approved; make improvements to our manufacturing process and product design; launch the TBI-002 trial or conduct other trials of the PoNS device; pursue further regulatory approvals; maintain, expand and protect our intellectual property portfolio; and add additional personnel. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital expenditure or sell certain assets, including intellectual property, and we may be forced to cease or wind down operations, seek protection under the provisions of the U.S. Bankruptcy Code, or liquidate and dissolve our Company.

Our ability to raise additional capital may be adversely impacted by global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

Off-Balance Sheet Arrangements

In September 2018, we entered into an exclusive strategic alliance agreement with HTC and Heuro. Under the terms of the agreement, the parties developed a clinic system to facilitate the commercialization of the PoNS Treatment in Canada. Prior to October 30, 2019, the arrangement provided for HTC to pay us CAD$750 thousand in three annual payments of CAD$250 thousand beginning December 31, 2019, in consideration for the exclusivity right we granted to Heuro. We and HTC governed the agreement through a joint steering committee, and each funded up to 50% of Heuro's operating budget as agreed to by the joint steering committee and shared in the net profits and losses of Heuro on a 50/50 basis. This agreement was amended as a result of the acquisition of Heuro on October 30, 2019. Refer to Note 2 to our audited consolidated financial statements and related notes included elsewhere in this prospectus for more information.

To the best of management's knowledge, there are no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations or financial condition other than that described above and in Note 8 to our audited consolidated financial statements and related notes included elsewhere in this prospectus.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements that have been prepared in accordance with U.S. GAAP. This preparation requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. U.S. GAAP provides the framework from which to make these estimates, assumption and disclosures. We choose accounting policies within U.S. GAAP that management believes are appropriate to accurately and fairly report our operating results and financial position in a consistent manner. Management regularly assesses these policies in light of current and forecasted economic conditions. Actual results could differ from those estimates made by management. While there are a number of significant accounting policies affecting our financial statements, we believe the critical accounting policies involving the most complex, difficult and subjective estimates and judgments are: revenue recognition, stock-based compensation, derivative financial instruments, and goodwill and other intangible assets.

Revenue Recognition

In accordance with FASB's ASC 606, *Revenue from Contracts with Customers*, ("ASC 606"), we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to be entitled in exchange for those goods or services, in an amount that reflects the consideration which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

We apply the five-step model to contracts when we determine that it is probable we will collect substantially all of the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price, after consideration of variability and constraints, if any, that is allocated to the respective performance obligation when the performance obligation is satisfied.

License Revenue

Prior to the fourth quarter of 2018, we had not generated revenue. During the fourth quarter of 2018, as part of our exclusive strategic alliance agreement, we transferred a license to Heuro in order for it to develop the clinic systems to facilitate the commercialization of the PoNS Treatment in Canada. The license was a functional license as it had stand-alone functionality. As such, we recognized revenue once control transferred, which occurred in the fourth quarter of 2018 when regulatory approval of the PoNS device in Canada was obtained and the commercialization of the product, as defined within the agreement, began. The agreement provided to pay us CAD$750 thousand in three annual payments of CAD$250 thousand beginning December 31, 2019, in

consideration for the exclusivity right we granted to Heuro. We considered this to be a significant financing component and as such, the amount reflected in our consolidated statements of operations and comprehensive loss was discounted. The discount rate utilized to measure revenue and the related receivable was determined based on the rate that would be reflected in a separate financing transaction with the customer. During the fourth quarter of 2018, we recognized revenues of $0.5 million in license fees when we satisfied our performance obligation. As described in Note 2 to the consolidated financial statements, we modified our arrangement with HTC on October 30, 2019. License revenue will be recognized ratably over the ten year term as the performance obligation is met in connection with the Co-Promotion Agreement.

Product Sales, net

During the first half of 2019, product sales were derived from the sale of the PoNS device and certain support services including services from the use of the NeuroCatch™ device, which is owned by HTC and assesses electroencephalogram brain waves related to cognition of patients participating in the PoNS Treatment at neuroplasticity clinics in Canada. We acted in an agency capacity for services performed using the NeuroCatch device and remitted CAD$600 for each patient assessed with the NeuroCatch device. According to the supply agreement with each of these clinics, our performance obligation was met when we delivered the PoNS device to the clinic's facility and the clinic assumed title of the PoNS device upon acceptance. As such, revenue is recognized at a point in time. Shipping and handling costs associated with outbound freight before control of a product has been transferred to a customer are accounted for as a fulfillment cost and are included in cost of sales. Further, according to our arrangement with HTC and Heuro, we shared 50/50 with Heuro in fees from support services excluding the CAD$600 payment for an assessment using the NeuroCatch device. Subsequent to July 1, 2019, product sales were derived from the sale of the PoNS device alone as the NeuroCatch is sold directly to the neuroplasticity clinics in Canada by HTC. For the year ended December 31, 2019, we recorded $1.5 million in product sales net of $11 thousand for HTC's portion related to assessments using the NeuroCatch device. For the nine months ended September 30, 2020, the Company recorded $0.4 million in product sales. As described in Note 2 to the consolidated financial statements, we modified our arrangement with HTC on October 30, 2019. As of December 31, 2019, the control of the 55 PoNS devices included as consideration in the Heuro acquisition had not been transferred resulting in the fair value of the devices being recorded as deferred revenue of $0.4 million on the consolidated balance sheet. As of September 30, 2020, the control of 11 devices had been transferred resulting in recognition of revenue for these devices. The fair value of the remaining 44 devices is still recorded as deferred revenue on the condensed consolidated balance sheet. Revenue will be recognized for these devices as control is transferred. The only returns during 2019 and during the nine months ended September 30, 2020 were the result of warranty returns for defective products. These returns were insignificant and any future replacements are expected to be insignificant.

Fee Revenue

During the first half of 2019, our agreement with HTC and Heuro also entitled us to 50% of the franchise fees collected by Heuro from each franchise agreement Heuro executed with neuroplasticity clinics engaged in providing the PoNS Treatment. For the year ended December 31, 2019, we recognized $37 thousand as our 50% portion of the franchise fees. During the nine months ended September 30, 2020, the Company recognized $9 thousand of fee revenue related to engaging new neuroplasticity clinics to provide the PoNS Treatment. During the nine months ended September 30, 2019, the Company recognized $49 thousand of fee revenue associated with the Company's agreement with HTC and Heuro that entitled the Company to 50% of the franchise fees collected by Heuro from each executed franchise agreement. As of September 30, 2020 and December 31, 2019, the Company had no contract assets or liabilities on its condensed consolidated balance sheets related to the supply agreements with each clinic.

Stock-Based Compensation

We account for all stock-based payments and awards under the fair value-based method. We recognize our stock-based compensation expense using the straight-line method.

We account for the granting of stock options to employees and non-employees using the fair value method whereby all awards are measured at fair value on the date of the grant. The fair value of all employee-related stock options is expensed over the requisite service period with a corresponding increase to additional paid-in capital. Upon exercise of stock options, the consideration paid by the option holder, together with the amount previously recognized in additional paid-in capital is recorded as an increase to common stock. Stock options granted to employees are accounted for as liabilities when they contain conditions or other features that are indexed to other than a market, performance or service conditions.

Stock-based payments to non-employees are measured based on the fair value of the equity instrument issued. Compensation expense for non-employee stock awards are recognized over the requisite service period following the measurement of the fair value on the grant date over the vesting period of the award.

We use the Black-Scholes option-pricing model to calculate the fair value of stock options. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. Changes in these assumptions can materially affect the fair value estimate.

Derivative Financial Instruments

We evaluate our financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815, *Derivatives and Hedging*. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market at each balance sheet date and recorded as a liability and the change in fair value is recorded in the consolidated statements of operations and comprehensive loss. Upon conversion or exercise of a derivative financial instrument, the instrument is marked to fair value at the conversion date and then that fair value is reclassified to equity.

The classification of derivative financial instruments, including whether such instruments should be recorded as a liability or as equity, is re-assessed at the end of each reporting period. Derivative financial instruments that become subject to reclassification are reclassified at the fair value of the instrument on the reclassification date. Derivative financial instrument liabilities are classified in the consolidated balance sheet as current or non-current based on whether or not the right to exercise or settle the derivative financial instrument lies with the holder.

We use the Black-Scholes option-pricing model to value derivative financial instrument liabilities. This model uses Level 3 inputs in the fair value hierarchy established by ASC 820—*Fair Value Measurement*.

Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair values underlying net assets acquired in an acquisition. All of our goodwill as of December 31, 2019 is the result of the Heuro acquisition. Goodwill is not amortized, but rather will be tested annually for impairment or more frequently if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We will test goodwill for impairment annually in the fourth quarter of each year using data as of October 1 of that year.

Goodwill is allocated to, and evaluated for impairment at our one identified reporting unit. Goodwill is tested for impairment by either performing a qualitative evaluation or a quantitative test. The qualitative evaluation is an assessment of factors to determine whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. We may elect not to perform the qualitative assessment for our reporting unit and perform the quantitative impairment test. The quantitative goodwill impairment test requires us to compare the carrying value of the reporting unit's net assets to the estimated fair value of the reporting unit.

If the estimated fair value exceeds the carrying value, no further evaluation is required, and no impairment loss is recognized. If the carrying amount of a reporting unit, including goodwill, exceeds the estimated fair value, the excess of the carrying value over the estimated fair value is recorded as an impairment loss, the amount of which is not to exceed the total amount of goodwill allocated to the reporting unit.

Definite-lived intangibles consist principally of acquired customer relationships and proprietary software as well as internally developed software. All are amortized straight-line over their estimated useful lives. We review long-lived assets, including definite-lived intangible assets subject to amortization, for impairment whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Recoverability is assessed for the carrying value of assets held for use based on a review of undiscounted projected cash flows. Impairment losses, where identified, are measured as the excess of the carrying value of the long-lived asset over its estimated fair value as determined by discounted projected cash flows.

Recently Issued Accounting Pronouncements

The information set forth in Note 2 "Summary of Significant Accounting Policies" to our interim unaudited condensed consolidated financial statements included elsewhere in this prospectus is incorporated herein by reference.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies. Our status as an "emerging growth company" ended on December 31, 2020.

BUSINESS

Overview

We are a neurotechnology company focused on neurological wellness. Our purpose is to develop, license or acquire non-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

Our first product, known as the Portable Neuromodulation Stimulator, or PoNS™("PoNS"), is authorized for sale in Canada as a class II, non-implantable medical device intended as a short term treatment (14 weeks) of gait deficit due to symptoms from multiple sclerosis ("MS") and balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy, or PoNS Treatment™. It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for de novo classification and clearance by the U.S. Food and Drug Administration (the "FDA") as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

PoNS Device

The PoNS device is a non-implantable investigational medical device comprised of a controller and a mouthpiece that are connected by a cord. The controller is worn around the neck and the mouthpiece sits on the tongue during treatment. PoNS Treatment, or the "Treatment", utilizes the PoNS device in conjunction with targeted physical and / or cognitive therapy. The therapy consists of condition specific exercises for movement control, balance and gait training, and breathing and awareness training that are designed to focus on the individual patient's functional deficits. The Treatment is 14 weeks and is delivered through authorized PoNS treatment clinics by certified PoNS trainers, with the first 2 weeks in a clinic. The remaining 12 weeks are completed at home with weekly clinic visits to monitor progress, assess improvements and ensure the therapy level is still appropriate. When the device is on, the 143 gold-plated electrodes on the mouthpiece send mild electrical signals to the tongue. These impulses stimulate nerves in the tongue that have direct pathways to the brain, through the brain stem. The combination of mild stimulation with therapeutic activities may enhance the neuroplastic effect, potentially resulting in functional improvements in balance and gait. During each clinic visit and at the end of the 14-week Treatment, the clinic downloads the PoNS usage data from the device and reviews it with the patient. This usage data in combination with the detail of the completed assessments gives the clinician and the patient a unique and powerful method to assess treatment progress. The patient re-initiates their Treatment sessions under the supervision of the clinicians through regular check ins.

Clinical research has shown that translingual neurostimulation activates two major cranial nerves –the trigeminal nerve, and the facial nerve, which creates a flow of neural impulses that are delivered directly into the brain stem and cerebellum – the main control centers for multiple life functions including sensory perception and movement. From the brain stem, these impulses travel throughout the brain and activate or reactivate neurons and structures involved in human function. Researchers believe that targeted physical therapy with neurostimulation can initiate changes in the brain, supporting the rebuilding and reorganizing (neuroplasticity) of multiple areas of the brain.

Design

The PoNS device is ergonomically designed for patient comfort, is relatively light, contains a replaceable hygienic mouthpiece and a rechargeable battery with built-in technology to allow for tracking of the patient's usage, including time and intensity of treatments. See Figure 1.

Figure 1
The Portable Neuromodulation Stimulator, PoNS device

The mouthpiece of the PoNS device sits on the front third of the tongue and is held in place by the lips and closed mouth. See Figure 2.

Figure 2

A rechargeable lithium polymer battery with built-in charge safety circuitry provides power. While the voltage and pulse timing to each electrode are programmed into the device and cannot be altered, the user can adjust the stimulus intensity, which is achieved by adjusting the electrical pulse width. The sensation produced by the mouthpiece is similar to the feeling of drinking a carbonated beverage. The patented waveform is specifically designed to minimize the potential for tissue irritation.

Overview of Multiple Sclerosis and Current Available Treatments

Multiple Sclerosis, or MS, is currently classified as an autoimmune disease of the central nervous system. The disease attacks the myelin, the protective covering of the nerve necessary for the transmission of nerve impulses through nerve fibers, causing inflammation and often damaging the myelin. Damage to the myelin is

variable, depending on the course of the disease, which influences the type and severity of symptoms. MS is unpredictable and can cause symptoms such as extreme fatigue, lack of coordination, weakness, tingling, impaired sensation, vision problems, bladder problems, cognitive impairment and mood changes. Its effects can be physical and emotional with a substantial financial burden. Currently there is no cure and patients with MS experience a progressive decline in health over time. There are a variety of treatments available for MS, some of which are experimental, including pharmaceutical, dietary, and surgical, which may or may not be covered by government or private health insurance.

Findings from a National MS Society study estimate that nearly 1 million people in the United States are living with MS and 93,000 in Canada. The National MS Society estimates that 2.3 million people live with MS globally. The United States and Canada have the highest rates of MS, with 309 cases per 100,000 in the United States, and 291 cases per 100,000 in Canada, respectively. Given the nature of this neurodegenerative disease, these individuals and their caretakers are active in exploring treatment options that may resolve or delay the progression of symptoms. There is also a well-established advocacy framework.

A 2016 economic analysis of MS found the total lifetime costs per person with MS to be $4.1 million, with average yearly healthcare costs ranging from $30 thousand to $100 thousand based on the severity of the disease. Since the exact cause of MS is still unknown, there is no known prevention. Although there is no cure for MS yet, treatments can manage symptoms. MS medications are designed to lessen the frequency of relapses and slow the progression of the disease, but none have proven to halt progression of the disease.

While there are several disease-modifying medications approved by the U.S. Food and Drug Administration to treat MS, only one drug approved by FDA and Heath Canada, Ampyra® (dalfampridine), is indicated for the improvement of gait speed in patients with MS, which offers the closest comparison to the effects of PoNS Treatment on improvement in gait.

Overview of mmTBI and Current Available Treatments

There are an estimated 14.5 million people globally, with over 1.5 million in the United States and 350,000 in Canada, living with balance deficit due to mmTBI. Every year in Canada and the United States there are approximately 20,000 and 420,000 newly diagnosed mmTBIs, respectively, resulting in balance deficit. This condition often has a significant impact on one's quality of life, negatively affecting independence, employability, productivity, mental health and participation in the community. Rehabilitation is often required following a mmTBI for resulting motor, cognitive and behavioral impairments. The current standard of care to address balance issues following a mmTBI is physical therapy. While physical therapy can help to promote balance recovery, individuals are often unable to return to their full function and are left living with a balance deficit.

Prior to the development of the PoNS device, there were no treatments available that were clinically proven and indicated to treat long-term balance deficit. A few studies have suggested that physical therapy aimed at improving balance and gait may be mildly effective for rehabilitation in the mmTBI population. However, to our knowledge, no mid-to-late stage clinical studies have reported improvements in function of the magnitude that would be considered evidence of systematic recovery of normal function, nor have any studies proven that physical therapy alone has a lasting effect on balance and gait. Given the small number of published studies, the small number of patients enrolled in the studies of which we are aware, the varying range of interventional protocols employed in such studies and the lower levels of study design, it is difficult to draw any conclusions regarding the effectiveness and dosing parameters of using physical therapy alone for the treatment of balance deficit following mmTBI. Consequently, we believe that there is a large potential commercial opportunity for the PoNS Treatment in the treatment of balance deficit due to mmTBI. Our goal is to establish the PoNS Treatment as the standard of care for this condition all over the world.

PoNS Clinical Trials and Scientific Support in MS

There are two peer reviewed published clinical trials reporting on the results of clinical trials comparing active PoNS + PT vs Placebo PoNS + PT in subjects with mild and moderate MS. (*Tyler et al. Journal of NeuroEngineering and Rehabilitation 2014, 11:79 and Leonard et al. Multiple Sclerosis Journal Experimental, Translational and Clinical January-March 2017: 19 DOI: 10.1177/ 2055217317690561)*

Summary results of the Tyler study in 20 patients with mild and moderate MS:

- In a comparison of the Dynamic Gait Index (DGI), a measure of the ability to walk, after 14 weeks of treatment of 10 subjects treated with active PoNS + PT Vs 10 subjects treated with placebo PoNS + PT
- Results showed a statistically significant change ($p<0.005$) in favor of the Active PoNS group.

Summary results from the Leonard study in 14 patients treated with mild and moderate MS:

- At week 14 there was a statistically significant improvement $p=0.001$ in the Sensory Organization Test (SOT), a test of subject's ability to balance, versus baseline for the 7 subjects in the active PoNS treated group and non-significant change in the 7 subjects in placebo PoNS treated group vs baseline.

Summary of Real-World Evidence in MS patients treated with PoNS in Canada.

- Treatment outcomes for patients treated in Canada are captured in the company developed validated data capture system. 39 patients with MS were treated with PoNS in Canada between March 2019 and September 2019.
- Using all available data from the treated MS patients, the mean improvement from baseline to Week 14 in the FGA (functional gait assessment) was 4.53 (95% CI 3.35 to 5.72). Based on observed data, the median improvement was 5 points.
- 56.7% had an improvement at Week 14 greater than or equal to 4 points, the minimum detectable change. This finding is remarkable given that the RWE data set consisted of patients with chronic MS with long durations of disease.
- Given the excellent safety profile, these data support a positive benefit risk ratio in the real-world setting.

PoNS Clinical Trials and Scientific Support in mmTBI

PoNS Registrational Clinical Trial in mmTBI

We completed our registrational clinical trial of the PoNS Treatment for persons with mmTBI in 2017. It was a double-blind randomized, controlled study of the safety and effectiveness of the PoNS Treatment using translingual noninvasive stimulation in participants with balance deficit due to mmTBI.

The trial was launched in 2015 in conjunction with the U.S. Army Medical Research and Materiel Command, or the USAMRMC, and was conducted at seven sites in the United States and Canada. The trial evaluated 122 randomized participants between the ages of 18 and 65 years. Each participant received five weeks of treatment, two weeks in clinic and three weeks at home. The treatment consisted of standardized targeted physical therapy geared toward the functional capability of each individual participant. Enrolled participants worked with a certified PoNS trainer and were randomized to receive either a high-frequency pulse, or HFP, (25.7 million pulses per 20-minute treatment) or a low-frequency pulse, or LFP, (13,728 pulses per 20-minute treatment) PoNS device. While the HFP and the LFP devices were identical, the frequency of the pulses was different.

Trial Design

All participants provided a prior neuroradiologic report (obtained at least one year after the most recent mmTBI), if available, and completed demographic and quality of life surveys and a medical history during an

initial screening visit. Participants who met the initial screening entrance criteria were scheduled for an MRI of the head, a neuropsychiatric evaluation, the NeuroCom Sensory Organization Test, or SOT, to evaluate balance, and a 20-minute walk on the treadmill to evaluate fitness. Key eligibility criteria to participate in the study included the following:

- Male or female, 18 to 65 years of age.
- At least 1-year post most recent mmTBI at the time of screening.
- Had participated in a focused physical rehabilitation program for mmTBI and had been deemed by the treating clinician to have reached a plateau.
- Had a balance disorder SOT composite score of at least 16 points below the normative value for the participant's age.
- Stable neurologic status, as determined from the participant's medical records and the trial physician's opinion based on no new or changing symptoms.

Participants meeting all the eligibility criteria, and who were not disqualified by exclusion criteria applicable to the trial, were enrolled and randomly assigned in blocks of four to receive an HFP or LFP device. Randomization occurred at each site, according to the randomization plan developed by the clinical research organization. An objective balance assessment was performed using the composite score from the SOT, which measures balance using computerized sensors that objectively measure participants' ability to maintain balance under six different conditions. The SOT is a widely used measurement tool for balance disorder associated with TBI and was used as the primary efficacy endpoint for the trial. According to published clinical trial data, patients that received physical therapy alone to treat balance deficit related to mmTBI improved by an average of ten to 13 points on the SOT scale, a 0 to 100 scale, and clinical experience shows those patients tend to drift back to baseline levels when physical therapy is discontinued. On average, participants entered the trial with an SOT composite score of approximately 40, which is a score that indicates substantially compromised functional balance. In the trial, an SOT responder was defined as a participant with an improvement of at least 15 points in his/her SOT composite score from baseline to the end of five weeks of PoNS Treatment, a level of change that to our knowledge, has not been achieved in clinical trials of patients with mmTBI-related balance disorder undergoing standard of care physical therapy.

Trial Results

The trial's statistical analysis plan stated that, if the outcome of the primary effectiveness endpoint showed that PoNS Treatment in the HFP and LFP arms both produced responses of greater than 15 points on the SOT composite score that were not significantly different from one another, the secondary endpoint would be calculated by combining the two groups and comparing the response to baseline at week two and week five. This would imply that both devices had a clinical effect.

The primary effectiveness endpoint demonstrated a trend toward a higher responder rate in the HFP arm (with 71.2% of subjects experiencing a greater than 15 point improvement on the SOT composite score) than in the LFP arm (with 63.5% of subjects experiencing a greater than 15 point improvement on the SOT composite score), $p<0.081$. The primary effectiveness endpoint was not reached because of the significant therapeutic effect observed in the LFP arm. Because both arms produced responses of greater than 15 points on the SOT composite score that were not significantly different from one another, the secondary effectiveness endpoint was calculated per the statistical analysis plan, as described above. The secondary effectiveness endpoints demonstrated statistically and clinically significant increases in SOT composite scores:

- The mean improvement at two weeks for the pooled arms was 18.3 points, $P<0.0005$.
- The mean improvement at five weeks for the pooled arms was 24.6 points, $P<0.0005$.

Since the majority of patients who have a balance disorder associated with mmTBI are subjected to a higher risk of falls and headaches, the primary safety endpoint was an improvement in the frequency of falls as determined by daily event recording on the participant data case report form during the in-clinic phase of the study (week two). The secondary safety endpoint was the frequency and severity of headaches, as measured by the Headache Disability Index at baseline and at the end of treatment, which was at week five.

- We successfully met the primary and secondary safety endpoints as measured by a decrease in falls at week two a decrease in headaches at week five, respectively, in both treatment groups.
- There were no serious device related adverse events.

PoNS Long-Term Treatment Trial in mmTBI: A 26-Week Study

This study was performed to understand the durability of response to the PoNS Treatment. This double-blind randomized controlled study in patients with mmTBI was completed in 2017 at the Tactile Communication Neurorehabilitation Laboratory at the University of Wisconsin-Madison and was sponsored by the U.S. Army. The study was conducted with 22 and 21 participants randomized to the HFP and LFP PoNS Treatment arms, respectively. Participants underwent 14 weeks of active treatment identical in format to the treatment regime in our registrational clinical trial described above, followed by a 12-week washout period when participants discontinued the PoNS Treatment and were told to resume normal daily lifestyles with no specified physical therapy regime. SOT composite scores were captured at specific time points throughout the study, including at 14 weeks and after the 12-week washout (26 weeks).

Highlights of the study results were as follows:

- There was no statistical difference between the HFP and LFP PoNS Treatment arms mirroring the results of the registrational clinical trial.
- On average, participants entered the study with an SOT composite score of approximately 40, which is a score that indicates substantially compromised functional balance.
- At the end of 14 weeks of active treatment with the HFP PoNS arm, patients showed improvements on average of 29.8 points on the SOT composite score.
- After the 12-week washout period, the participants, on average, maintained the same SOT composite score as after 14 weeks of PoNS treatment.

Conclusion:

- The study demonstrated that the PoNS Treatment could, on average, allow patients with mmTBI who had balance deficit and other injury-related functional disabilities, achieve an SOT composite score in the normal range in 14 weeks and maintain that benefit after a 12-week washout period. We believe that this data supports the durability of the response to the treatment and the potential restoration of the balance system. Furthermore, in a subset of nine participants, sequential magnetic resonance imaging, or MRI, scans were performed that showed increased grey matter volume in the cerebellum and elsewhere, commensurate with improved balance.

Overall Conclusion From the Two mmTBI Trials.

We believe the most significant observations from the two mmTBI trials are:

- Our registrational and long-term treatment trials combined were the largest non-implantable neuromodulation trials in balance and gait deficit due mmTBI ever performed.
- Participants who had a profound, chronic balance disorder resistant to conventional physical therapy, and with a prognosis of a lifetime of this disability were, on average, in the normal range of balance following the 14 weeks of treatment.

- In a subset of nine participants, MRI scans revealed structural changes in the brain resulting from the neuromodulation inducing neuroplastic effect.
- The PoNS Treatment in one data set also resulted, on average, in patients maintaining the improvement for at least a 12-week period suggesting a permanent improvement in participants' balance issues.
- There were no differences in clinical outcomes across the clinical trial sites performing both trials.
- There were no differences at baseline in age, sex, time from injury, amount of previous physical therapy, level of disability or adherence to therapy in each of the treatment groups.
- The difference in therapeutic effect noted between high and low frequency pulse groups suggests that there was an independent device effect.

Regulatory Status Worldwide

Canadian Regulatory Status: mmTBI and MS

On October 17, 2018, we received our Canadian marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for use as a short-term treatment (14 weeks) of balance deficit due to mmTBI.

On March 18, 2020, we received marketing authorization from Health Canada allowing us to commercialize the PoNS device in Canada for the treatment of gait deficit in patients with mild and moderate MS symptoms. Our market authorization application comprised objective statistical evidence as well as independently reviewed clinical research analysis. We believe this label expansion will significantly expand our addressable market opportunity in Canada to include a patient population that is motivated to pursue treatment options which may resolve or delay the progression of MS gait deficit symptoms.

US Regulatory Status: MS

In March 2020, we announced that based on the quality of the data included in our MS submission package to Health Canada and the significant unmet needs of those afflicted with MS, we are prioritizing the MS indication as the pathway to pursue our first U.S. clearance of the PoNS device. We believe the existing published data and real-world evidence with use of the PoNS for the treatment of gait disorder in patients with mild and moderate MS are sufficient to demonstrate a favorable risk/benefit profile, as required for de novo classification and clearance to enable US marketability. Novel treatments for MS are highlighted as a specific target of the FDA as a high unmet medical need disease.

On May 7, 2020 we received Breakthrough Designation for the PoNS device as a potential treatment for gait deficit due to symptoms of Multiple Sclerosis ("MS"), to be used as an adjunct to a supervised therapeutic exercise program. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and de novo classification and clearance, consistent with FDA's mission to protect and promote public health.

The Breakthrough Devices Program replaces the Expedited Access Pathway and Priority Review for medical devices. The FDA considers devices granted designation under the Expedited Access Pathway to be part of the Breakthrough Devices Program.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

Breakthrough Device Designation does not change the requirements for approval of an application for a marketing authorization under section 510(k) of the Food, Drug, and Cosmetic Act.

On August 4, 2020, we submitted our request to the FDA for de novo classification and clearance of the PoNS device for the treatment of gait deficit due to symptoms from MS, to be used as an adjunct to a supervised therapeutic exercise program in patients over 18 years of age.

On October 19, 2020, we announced that we received a request for additional information from the FDA related to the Company's request for de novo classification and clearance of the PoNS device. During the substantive review phase of a request for de novo classification and clearance, FDA may request additional information in order to obtain information necessary for the FDA to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted. The FDA's request for additional information was received approximately 75 days from the submission date, which is consistent with FDA's expected timing for review of a Breakthrough Designated product, such as the PoNS device. The FDA's request for additional information includes requests for additional analysis of clinical data and proposes certain labeling modifications. On January 11, 2021, we announced that we submitted our formal response to the FDA's request for additional information.

US Regulatory Status: mmTBI

Our U.S. regulatory strategy initially focused on pursuing de novo classification and clearance of the PoNS device from the FDA for the treatment of balance deficit due to mmTBI.

We submitted a request for de novo classification and clearance of the PoNS device to the FDA for this indication in August 2018. This request was supported by data from two of our clinical trials in mmTBI, including our registrational trial, TBI-001.

In April 2019, we announced the FDA had completed its review and had denied our request for de novo classification and clearance of the PoNS device for the treatment of balance deficit due to mmTBI. In reaching its conclusion, the FDA noted, via a denial letter, that although the safety profile of the PoNS device is acceptable, the FDA did not have sufficient information to discern the relative independent contributions of the PoNS device and physical therapy on the improvements from baseline. The FDA noted that we could generate additional data to address its concerns and resubmit our application.

In October 2019, we had a pre-submission meeting where the FDA provided feedback needed to help complete the design of a new clinical trial intended to address the FDA's request for a trial that demonstrates the benefit of the PoNS Treatment compared to physical therapy alone. In January 2020, we received the FDA's feedback on the minutes from the October 2019 pre-submission meeting. In its feedback, the FDA provided post-meeting notes with specific recommendations regarding the trial design that were not discussed in the October 2019 pre-submission meeting.

Based on the receipt of the FDA's final minutes from the pre-submission meeting, we finalized our clinical protocol for a new trial, TBI-002, intended to support a request for de novo classification and clearance of the PoNS device. TBI-002 will be a multi-center, randomized trial in the U.S. and Canada consisting of 103 subjects with balance deficit due to mmTBI. Although TBI-002 will take longer and be more costly than the design that we had discussed at our October 2019 pre-submission meeting, we believe that the chances of obtaining FDA de novo classification and clearance will be significantly increased if we incorporate the FDA's pre-submission feedback into this next trial design.

TBI-002 will proceed in two phases: a run-in phase, followed by a treatment phase. During the run-in phase, all subjects will receive 5 weeks of physical therapy alone. Subjects will then be randomized and assigned to one of two groups in the treatment phase where subjects will either receive up to 10 weeks of physical therapy with the PoNS device or 10 weeks of physical therapy without the PoNS device. The primary effectiveness endpoint of TBI-002 will be a responder analysis.

Prior to the COVID-19 pandemic, our expectation was that we would move forward with the revised protocol and estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended, and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications, including stroke, cerebral palsy, Parkinson's disease, baby boomers balance, and neurological wellness.

European Regulatory Status

In December 2018, we submitted an application for a CE Mark, which, if approved, would allow us to market the PoNS device in the EU. During the second quarter of 2019, we engaged with regulators in Europe to answer questions that we received from them as part of their review of our PoNS device for CE marking. In August 2019, we withdrew our application from the EU marketing process due to uncertainty in Europe caused by the switch from the Medical Device Directive, or MDD, to the Medical Device Regulation, or MDR, Brexit, and the withdrawal of Lloyd's Register Quality Assurance, our notified body, from the EU notified body business. We have engaged G-MED NA (North America) as our new ISO registrar and new notified body and will reconsider submitting to the EU when conditions stabilize.

Australian Regulatory Status

In the third quarter of 2019 we initiated the submission of our application to the TGA. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. We are currently awaiting additional feedback from the TGA on our application.

Partnerships and Agreements

U.S. Army Partnership

Between 2013 and 2015, we entered into a series of agreements with the U.S. Army to determine if the PoNS Treatment could be developed for commercial use in the treatment of service members with balance deficit related to mmTBI, or the U.S. Army Agreement. Under the U.S. Army Agreement, we were the sole regulatory sponsor and oversaw and executed all required clinical studies. The U.S. Army reimbursed us for the initially budgeted costs related to the registrational clinical trial of the safety and effectiveness of the PoNS Treatment for balance deficits related to mmTBI, up to a maximum amount of $3.0 million.

In November 2018, the U.S. Army Combat Capabilities Development Command Army Research Laboratories, or Army Laboratories, notified us of their intention to terminate the Master Cooperative Research and Development Agreement, or the CRADA, effective December 31, 2018. In December 2018, the U.S. Army notified us that it was amending the U.S. Army Agreement to provide that our obligations under the contract were satisfied upon our submission of an application for marketing authorization of the PoNS device to the FDA.

Our satisfaction of the U.S. Army Agreement and the termination of the CRADA concluded our formal contractual relationships with the U.S. Army. We are currently focusing on partnering with the relevant departments in the U.S. Department of Defense, or DOD, and U.S. Department of Veterans Affairs, or Veterans Affairs and other independent advocacy groups, to obtain reimbursement, upon FDA marketing authorization, for U.S. military personnel using our PoNS Treatment.

As of December 31, 2018, we received a total of approximately $3.0 million with respect to reimbursements for expenses owed to us for completion of development milestones. All reimbursement amounts received were credited directly to research and development expenses.

Canadian Strategic Alliance

In September 2018, we entered into an exclusive strategic alliance agreement with Health Tech Connex, Inc., or HTC, and Heuro Canada Inc., or Heuro, a newly formed wholly owned subsidiary of HTC, to establish

three founding clinics to treat patients and create a replicable model for future clinic expansion. Under the terms of the agreement, the parties developed a clinic system to facilitate the commercialization of the PoNS Treatment in Canada. Under the terms of the agreement, the parties contracted with the clinics and developed a model for the clinics to deliver clinical services, featuring the PoNS Treatment, to manage neurological conditions.

During the second quarter of 2019, we entered into the clinic expansion phase of the alliance with the addition of up to three new PoNS-authorized clinics, bringing the total number of clinics authorized to treat patients with the PoNS device to five in Canada.

Prior to October 30, 2019, the exclusive strategic alliance agreement provided for HTC to pay us CAD$750 thousand in three annual payments of CAD$250 thousand beginning December 31, 2019, in consideration for the exclusivity right we granted to Heuro. We and HTC governed the agreement through a joint steering committee, and each funded up to 50% of Heuro's operating budget as agreed to by the joint steering committee and shared in the net profits and losses of Heuro on a 50/50 basis.

During the third quarter of 2019, we engaged with HTC through the joint steering committee in discussions regarding the future development of the commercialization of the PoNS device and PoNS Treatment in Canada. As we worked with Heuro to expand the commercial infrastructure, the complexity and feasibility of using a franchise model to build a market for PoNS including the physical therapy component became challenging. By acquiring Heuro, as noted below, we were able to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

On October 30, 2019, we and HTC entered into a Share Purchase Agreement, or the SPA, whereby we, through our wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately $1.6 million was paid to HTC, which included (1) the repayment to HTC for their investment in the set-up of Heuro's initial commercial infrastructure including, the establishment of five authorized PoNS clinics across Canada, (2) the current market value of 55 PoNS devices which we also are to provide to HTC under the SPA, (3) the CAD$750,000 receivable from the September 2018 strategic alliance agreement and (4) the sale of exclusivity rights granted to HTC in the Co-Promotion Agreement, as defined below, to provide PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia.

In connection with the Share Purchase Agreement, on October 30, 2019, we entered into a Clinical Research and Co-Promotion Agreement with HTC, or the Co-Promotion Agreement, whereby each company will promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. This co-promotion arrangement terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. The co-promotion arrangement terminated on December 31, 2020. Also, subject to certain terms and conditions, we granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS-authorized clinic since February 2019. HTC will purchase the PoNS devices for use in these regions exclusively from us and on terms no less favorable than the then-current standard terms and conditions. This exclusivity right has an initial term of ten years, renewable by HTC for one additional ten year term upon sixty days' written notice to us.

A&B Asset Purchase Agreement

In October 2015, we entered into a strategic agreement with A&B (HK) Company Ltd., or A&B, an investment and development company based in Hong Kong for the development and commercialization of the PoNS Treatment in China, Hong Kong, Macau, Taiwan and Singapore, collectively referred to as the Territories. The agreement transferred ownership of certain of our Asian patents, patent applications, and product support material for the PoNS device from us to A&B and granted to A&B, among other things, an exclusive license to market, promote, distribute and sell the PoNS device solely within the Territories. Pursuant to the agreement, A&B has assumed all development, patent (both application and defense), future manufacturing, clinical trial,

and regulatory clearance costs for the Territories. A&B and us will share and transfer ownership of any intellectual property or support material (developed by either party) for each of our respective geographies.

In connection with the agreement, A&B agreed to provide us with a $7.0 million funding commitment, consisting of an initial $2.0 million convertible promissory note and a $5.0 million funding commitment. On October 9, 2015, we received the conversion notice on the promissory note and, on November 10, 2015, we issued 11,904 shares of common stock at a price of $168.00 per share and 5,952 warrants exercisable at $252.00 per share for a period of three years from the date of issuance. On December 29, 2015, we drew down the $5.0 million funding commitment through the January 7, 2016 issuance of 31,746 shares of common stock at a price of $157.50 per share and 15,873 warrants exercisable at $236.25 per share for a period of three years from the date of issuance. In November 2017, A&B exercised 5,952 warrants at a price of $252.00 per share and we received gross proceeds of $1.5 million. During the first quarter of 2018, A&B exercised its remaining 15,873 warrants at a price of $236.25 per share and we received gross proceeds of $3.8 million.

In August 2018, A&B executed a transfer agreement whereby A&B transferred all the assets under the A&B asset purchase agreement with us to China Medical Systems Medical Limited, or CMS, a Malaysian based Hong Kong listed company and an affiliate of A&B. In February 2019, we executed a novation deed whereby CMS irrevocably assigned and transferred all of its rights, obligations and assets under the transfer agreement to CMS Medical Hong Kong Limited, a Hong Kong-based investment holding company principally engaged in the manufacture, marketing, promotion and sales of pharmaceutical products. We are currently working with CMS in providing regulatory support of its application to the National Medical Products Administration for marketing authorization in China.

Product Development, Manufacturing and Logistics Services

In January 2017, we entered into an agreement with Cambridge Consultants LLC, or Cambridge, pursuant to which Cambridge assumed responsibilities for key aspects of the design and development of the PoNS device. As part of the agreement, Cambridge will validate the performance of the engineering, design verification testing and product documentation to support our FDA submission. Cambridge will also assist us in the identification of, and transition to, our commercial-scale manufacturer.

On December 29, 2017, we selected Key Tronic Corporation, or Key Tronic, as our contract-manufacturing partner for the PoNS device after a competitive selection process. The commercial design of the PoNS device will be manufactured and assembled at Key Tronic's facilities located in Oakdale, Minnesota. Key Tronic manufactured devices for engineering and design verification testing and for our FDA submission as well as commercial devices for launch inventory. Key Tronic has multiple locations across the United States, Mexico and China with back-up manufacturing capabilities to help mitigate the risk of a single source provider. We remain ultimately responsible for the compliance of our submissions and products, and activities performed on our behalf.

We place an emphasis on protecting our patented technology, trade secrets and know-how and only share confidential information on an as needed basis. Key Tronic is registered as a medical device manufacturer in good standing with the FDA and along with Cambridge are certified in accordance with International Organization for Standardization, or ISO, 13485, a comprehensive quality management system for the design and manufacture of medical devices.

On November 30, 2016, HMI received our ISO 13485:2003 certification, which was updated to the 2016 version of the standard during the fourth quarter of 2018 along with receiving our Medical Device Single Audit Plan, or MDSAP, for the United States and Canada, with the scope of the MDSAP certification expanded to include Australia during the third quarter of 2019.

In February 2019, we entered into an agreement with McKesson Specialty Care Distribution LLC, or McKesson, pursuant to which McKesson will provide a comprehensive array of logistical, account management

and related distribution services for the commercialization of the PoNS device in the United States. This agreement was terminated in the second quarter of 2019 following the FDA's denial of our request for de novo classification and clearance of the PoNS device.

Commercialization

Canada Commercialization Efforts

From a real-world results perspective, in Canada thus far, the collective experience of our patients that have completed the 14-week PoNS Treatment have been encouraging. Consistent with what we saw in our two clinical trials, one for 5 weeks and the other for 14 weeks, commercial TBI patients are demonstrating improvements in balance and gait within the first two weeks followed by continued improvement over the following twelve weeks. The majority of patients have a mean patient adherence to treatment of over 90% and showed significant improvement in their balance and gait with a meaningful clinical difference at the end of their treatment. The consistency of the patient results from our initial commercial experience supports our plans to expand access PoNS Treatment in Canada.

March 2019 marked the commercialization of our PoNS Treatment in Canada, where PoNS became the first and only device authorized by Health Canada for the treatment of balance deficit due to mmTBI. Throughout 2019 we made important progress in advancing and refining our commercialization strategy in Canada building access, awareness and credibility for the PoNS Treatment. These efforts, which were led by our local Canadian commercial team, included the establishment of our authorized clinic network throughout Canada, launching digital marketing campaigns, and building key opinion leader and advocacy networks.

During the third quarter of 2019, we made the strategic decision to change our business model in Canada in order to accelerate the adoption of our novel technology. On October 30, 2019, we acquired the Heuro Canada operating entity from HTC which allowed us to streamline the decision-making process and increase our ability to react to evolving market factors as the market for the PoNS Treatment is being developed.

On March 18, 2020, the Company received notification that its Canadian Class II license amendment application for the treatment of gait deficit in patients with mild and moderate symptoms from MS, when used in conjunction with physical therapy, was successful and received marketing authorization for PoNS from Health Canada.

Following in-depth market analysis and field intelligence, our Canadian commercial team began an expansion plan to increase the number of authorized PoNS clinics. In the first two months of 2020, we authorized 7 new clinic locations for a total of 14 clinic locations to provide PoNS Treatment across Canada. As of June 30, 2020, we had 20 clinic locations which we increased to 22 clinic locations as of September 30, 2020 and to 31 clinic locations as of December 31, 2020. There is a conscious shift in focus to driving patient throughput to these 31 clinics as we head into 2021. Sales performance in Canada continues to be impacted by the COVID-19 pandemic due to the space restrictions that the provincial governments have imposed as well as the risk tolerance of patients and therapists.

In collaboration with Toronto Rehabilitation Institute (part of University Health Network) we are continuing our clinical experience program, the results of which we will look to publish in 2021.

We continue to refine our go-to-market pricing model based on direct market feedback. Our modified pricing approach is focused on reducing the need for clinics and patients to pay large, upfront costs at the start of treatment. We have also experimented with various promotional pricing programs resulting in lower unit prices for both PoNS system purchases and mouthpieces in order to increase access to the PoNS treatment and drive market awareness which we expect to result in an increase in the volume of units sold, which was seen in the second half of 2020 when compared to the second half of 2019. We intend to keep the promotional pricing in place at least through the first quarter of 2021.

The value dossiers for mmTBI and MS that were created in mid-2020 to fully demonstrate in both scientific and financial terms, the merits of PoNS Treatment for claimants are now being implemented along with submissions from clinics on behalf of their patients. The dossier is provided to our clinics across Canada to submit as part of treatment plans with reimbursement applications to the payer community. Our reimbursement strategy for mmTBI continues to focus on the auto collision insurance and workers' compensation, or WC, market as well as long-term disability cases. Our reimbursement strategy for MS is focused on commercial insurers/extended health benefits.

As part of our overall PoNS Treatment strategy, we are also gathering comprehensive health economic assessments of treatment outcomes. These data will, in-turn, be used to support our applications for workers compensation, auto insurance and commercial insurance reimbursement initiatives in Canada, the United States and other markets around the world. The Canadian commercial experience will be extremely valuable to prepare us for our launches in the United States and internationally.

U.S. Pre-Commercialization Activities

In the United States, the PoNS device is an investigational device pending completion of our registrational clinical trial and submission to FDA on our application for de novo classification and clearance.

In this pre-commercial phase, we are working on the development of our commercial strategy focused on building relationships with key large neurorehabilitation centers, which focus on treatment of MS patients, pricing and reimbursement opportunities and generating important data on outcomes of the PoNS Treatment gathered from Real World Evidence generated from treatment of patients in Canada and ensuring that our scientific data is presented at many of the key national and international neurology and neuromodulation meetings. We believe this scientific dissemination will begin to pave the way to establishing the PoNS Treatment as the standard of care for the treatment of MS-related gait deficit following FDA marketing authorization, if received.

U.S. Clinical Experience Programs

In 2018, we initiated a series of clinical experience programs, or CEPs, to prepare for a potential U.S. commercial launch. Originally, our CEPs were designed learn from and build relationships with large key neurorehabilitation clinics, train and certify physical therapists and generate health economic, return-to-work and clinical data to inform our payer strategy.

Overall, we enrolled five clinic centers in the U.S. to carry out the CEPs: the Ohio State University Wexner Medical Center, a leading neurorehabilitation center located in Columbus, OH; Northwell Health's Feinstein Institute for Medical Research in Manhasset, NY; Oregon Health & Science University in Portland, OR; Kessler Institute for Rehabilitation and Kessler Foundation in Hanover, NJ; and the Baylor Research Institute in Dallas, TX.

Based on receipt of Canadian marketing authorization of our PoNS device earlier than anticipated, we were able rely on our early Canadian commercialization activities to provide us with the health economic, return-to-work and clinical data that we had planned to generate in the CEPs.

While we cancelled the CEP programs during 2019 after the denial by FDA, we have maintained solid relationships with the U.S. sites and expect several to become clinical trial sites for TBI-002, if pursued based on the availability of funding.

U.S. Commercialization

To commercialize the PoNS Treatment in the United States following FDA marketing authorization, if received, we plan to target a subset of neurorehabilitation centers that have been profiled as early adopters to

develop a network of PoNS certified neurorehabilitation centers that will be trained to deliver the PoNS Treatment. Care of patients with MS is concentrated in major neurorehabilitation centers that often have a network of outpatient rehabilitation clinics, where most of the PoNS Treatment will take place. We believe that a small, specialty sales force, calling on new technology review boards for trial and in-house physicians, neurologists, physiatrists and physical therapists, will be sufficient to drive trial and adoption of the PoNS Treatment in certified neurorehabilitation centers. Importantly, this focused strategy will also allow us to inspect whether we are generating patient outcomes similar to those seen in our clinical trials. We are planning to provide broad access and reimbursement for the PoNS Treatment over time. At launch, prior to the initiation of broad payer coverage, we anticipate the primary source of sales will be self-pay patients. We will support the cost of the PoNS Treatment by collaborating with third parties to provide self-pay patients with financing options as well as working with advocacy groups and charitable organizations to help self-pay patients access our technology. In addition,we intend to pursue Medicare coverage for PoNS under the CMS voluntary Medicare Coverage of Innovative Technologies (MCIT) pathway which is a proposed rule outlining a plan to cover FDA-designated breakthrough devices for up to four years from the date they receive U.S. marketing authorization. In general, we anticipate at least a 24-month window to obtain broad coverage and reimbursement among government and private payers. We plan to work in parallel with non-traditional payers, such as WC, auto insurance and the military, by engaging with them and providing them with relevant health economic and return-to-work data obtained through our Canadian commercial experience.

With the satisfaction of our clinical development contract with the U.S. Army, we are focusing on partnering with relevant departments in the DOD and Veterans Affairs to obtain reimbursement, upon FDA marketing authorization, for U.S. military personnel using our PoNS Treatment. These two initiatives, among others, offer the potential to expand access more expeditiously to these high-unmet need patient populations.

Commercialization in Other Markets

We submitted an application for a CE Mark in December 2018. In preparation for our launch in the United Kingdom, or UK, and the EU, we entered into a consulting agreement with a UK-based company with expertise in the development of new services in the healthcare industry to leverage local market insights to develop a comprehensive commercialization strategy and tactical plan for launch of the PoNS Treatment in the UK. As previously described, in August 2019, we withdrew our application from the EU marketing and will revisit our UK and EU commercialization upon receipt of marketing clearance.

We submitted an application to the TGA in Australia during the third quarter of 2019. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. We are currently awaiting additional feedback from the TGA on our application. We are working with consultants in Australia with expertise in market development to build our go-to-market strategy.

We also have marketing authorization to commercialize the PoNS Treatment in Russia and Uzbekistan. To date, we have not delivered any commercial devices in any of these territories and we will re-evaluate our strategic opportunities again at a later point in time.

COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread throughout the United States and around the world. The Company’s business, results of operations and financial condition have been adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS-authorized clinic locations across Canada from March until June 2020. Patients who

completed their initial training in the clinics prior to the closures have been able to continue working independently in the at-home portion of the treatment, with remote check-ins with their certified therapists. While all clinics have re-opened, they are all currently operating at reduced capacity within provincial guidelines, which limited operations to 50% capacity during the second half of 2020. Some patients have begun to return to these clinics for treatment, but patients have been and may continue to be less willing to return to the clinics due to COVID-19, impacting our commercial activities and our customer engagement efforts. We have expanded our services to include remote training and treatment, but the long-term viability of these remote programs is still being assessed. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 has led to further restrictions on clinic activities.

Additionally, while we do not currently have any clinical trials underway, we are running clinical experience programs in Canada and have experienced delays in the programs as trial participant attendance has generally decreased as a result of the pandemic, and clinics and clinical research sites have experienced delays and difficulties in recruiting and re-hiring clinical site staff, leading to further delays in the development and approval of the Company's product candidate. As noted above, prior to the COVID-19 pandemic, our expectation was that we would move forward with the launch of our TBI-002 trial and we had estimated that enrollment would begin in April 2020 with the completion of the trial and submission to the FDA in the second quarter of 2021. However, the launch of the TBI-002 trial has been temporarily suspended and we are evaluating our options for funding and timing to commence the trial or potentially look at other indications.

The COVID-19 pandemic and other outbreaks may cause delays in or the suspension of our business partners manufacturing operations, our research and product development activities, our regulatory workstreams, our research and development activities and other important commercial functions. We are also dependent upon our suppliers for the manufacture of our PoNS device, and in the second quarter of 2020, two of our business partners diverted resources towards other activities related to COVID-19, resulting in delays in the development and manufacturing of our product. Such diversion of suppliers' resources may occur again in the future, and the pandemic could limit our suppliers' ability to travel or ship materials or force temporary closure of facilities that we rely upon. Disruptions in business operations or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The extent to which the COVID-19 pandemic will continue to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. We do not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

Coverage and Reimbursement

With the clearance of the PoNS device for FDA marketing authorization, if received, we plan to engage with select payer segments to obtain coverage and reimbursement for the PoNS Treatment. We intend to combine evidence from our clinical trials and real-world experience from commercial clinics in Canada, to demonstrate the value proposition of the PoNS Treatment to payers and support favorable coverage and reimbursement decisions.

We believe that non-traditional payers may be among the earliest to provide coverage and reimbursement for the PoNS Treatment. Therefore, we are considering focusing initially on gaining coverage for the PoNS Treatment through WC payers. WC is an entitlement for injured workers, and payers are responsible for both medical and indemnity claims. Because these payers are responsible for both medical expenses and lost wages, they have an incentive to seek ways to help injured workers to return to work. As part of our commercial treatment program in Canada, we will collect both outcomes and return to work data, which we plan to utilize with WC payers to demonstrate both the clinical and economic value associated with the PoNS Treatment.

Similarly, military payers have an interest in reducing both medical costs and shortening the time to return to work for people who were injured while serving our country. We are working toward establishing relationships with thought leaders affiliated with the Department of Defense and Veterans Affairs, and will focus on obtaining reimbursement through this payer segment upon clearance. We anticipate that the same clinical and economic evidence that we will use with WC payers will also help to support gaining coverage and reimbursement for the PoNS Treatment military payers.

In parallel, we will engage with the Centers for Medicare & Medicaid Services, or CMMS, and select commercial payers. On January 12, 2021, the CMS stated that it is finalizing a new Medicare coverage pathway, Medicare Coverage of Innovative Technology, or "MCIT," for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years.

Competition

The neurostimulation market is predominantly comprised of invasive technologies that are not directly competitive with our technology. Our competitors in the industry are predominantly large, publicly-traded companies that have a history in the market, have significantly easier access to capital and other resources and have an established product pipeline. The combined clinical research and product development done by the industry, including by us and all of our competitors, is uncovering the secrets of neuromodulation which now establishes neurostimulation as a legitimate and scientifically validated approach to the treatment of neurological conditions, and accordingly, we expect for competition in the non-invasive space to grow in the future.

However, we believe that we will have the first-mover advantage in the non-invasive neurostimulation space.

We believe that the PoNS Treatment introduces an innovative target and method of stimulation because targeting the tongue for neurostimulation provides several advantages that competitively distinguish the PoNS Treatment, which are discussed below.

Advantages of the PoNS Treatment

We believe that the PoNS Treatment offers the following benefits over existing neurostimulation technologies:

- The PoNS Treatment stimulates the trigeminal nerve which developing science has implicated to be beneficial in some neurological disorder models. The PoNS Treatment stimulates the lingual part of the nerve through the tongue, while other technologies stimulate other branches of the trigeminal nerve. It is the largest branch, having the highest amount of nerve fibers of the three branches. We believe this will be an advantage in our therapy.
- Stimulating the tongue also allows for the simultaneous stimulation of a second cranial nerve found in the tongue, the facial nerve. The ability to stimulate more than one nerve alone differentiates us from our competition. However, it has not been scientifically proven that stimulating additional nerves adds to the efficacy or safety of the PoNS Treatment.
- The tongue has an anatomically unique surface with a high density of receptors, a consistently moist and conductive environment, constant pH, constant temperature and a direct connection to the brain through at least two cranial nerves.
- Scientific studies suggest that the trigeminal cranial nerves offer a high-bandwidth pathway for impulses to directly affect the central nervous system. The trigeminal nerves project directly onto several areas of the brain, primarily the brainstem (trigeminal and solitary nuclei), cerebellum, cochlear nuclei and spinal cord. Secondary targets include the limbic system, basal ganglia and thalamus. We believe that this range of projections will allow impulses to be sent through sites regulating dozens of functions.

- Unlike deep brain stimulation devices, implantable vagal nerve devices and other invasive forms of electrical stimulation, the tongue allows for neurostimulation to be delivered non-invasively and portably. This opens the door for integration of neurostimulation with a wide range of therapies previously unexplored for neurological rehabilitation.

Intellectual Property

Licensed Intellectual Property

Pursuant to the Second Amended and Restated Patent Sub-License, or the Sublicense Agreement, dated June 6, 2014 entered into between Advanced NeuroRehabilitation LLC, or ANR, and HMI, ANR has granted HMI a worldwide, exclusive license to make, have made, use, lease and sell devices utilizing certain patent applications, which are collectively referred to as the "Patent Pending Rights." The Patent Pending Rights relate to the PoNS device and include the following patents and patent applications, which cover a device that noninvasively delivers neurostimulation through the skin or intra-orally to the brain stem via various nerves including the trigeminal and facial nerves:

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
12/348,301	1/4/2009	Issued	8,849,407	9/30/2014	non-invasive neurostimulation of the skin combined with simultaneous physical therapy to provide neurorehabilitation of a patient to treat various maladies including, e.g., TBI, stroke and Alzheimer's disease
14/340,144	7/24/2014	Issued	8,909,345	12/9/2014	non-invasive neurostimulation within a patient's mouth combined with physical therapy to provide neurorehabilitation of a patient to treat various maladies including, e.g., TBI, stroke, and Alzheimer's disease
14/341,141	7/25/2014	Issued	9,020,612	4/28/2015	non-invasive neurostimulation within a patient's mouth combined with cognitive therapy to provide neurorehabilitation of a patient resulting in improved reading comprehension and increased attention span as well as the treatment various maladies including, but not limited to, TBI, stroke, and Alzheimer's disease
14/615,766	2/6/2015	Issued	9,656,078	5/23/2017	non-invasive neurostimulation within a patient's mouth combined with stimulation of the patient's vision, hearing, vestibular systems, or somatosensory systems for the treatment of tinnitus
14/689,462	4/17/2015	Issued	9,597,501	3/21/2017	non-invasive neurostimulation of a patient's skin combined with cognitive therapy to provide neurorehabilitation of a patient resulting in improved reading comprehension and increased attention span as well as the treatment various maladies including, e.g., TBI, stroke, and Alzheimer's disease
14/815,171	7/31/2015	Issued	9,597,504	3/21/2017	non-invasive neurostimulation of a patient's mouth combined with therapy to provide neurorehabilitation of a patient, with a focus on features of a neurostimulation device

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
15/207,029	7/11/2016	Issued	9,656,069	5/23/2017	non-invasive neurostimulation of a subject's oral cavity while the subject engages in an exercise in order to enhance a subject's proficiency in the exercise
15/283,894	10/3/2016	Issued	10,258,790	4/16/2019	non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance a subject's proficiency in the exercise
15/602,060	5/22/2017	Issued	10,328,263	6/25/2019	non-invasive neurostimulation within a patient's mouth or on a patient's skin combined with an exercise for treatment of a disorder affecting sleep patterns
61/019,061 (Provisional)	1/4/2008	Expired	N/A	N/A	N/A
61/020,265 (Provisional)	1/10/2008	Expired	N/A	N/A	N/A

U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,258,790; and 10,328,263 claim priority to U.S. Patent No. 8,849,407.

A U.S. provisional patent application provides the means to establish an early effective filing date for a later filed nonprovisional patent application. Therefore, though the two provisional applications have expired, they establish a priority date for U.S. Patent Nos. 8,849,407; 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,258,790; and 10,328,263, and any future filings that claim priority. We intend to file additional continuation applications in the United States Patent and Trademark Office, or USPTO, claiming priority to U.S. Provisional Patent Application Nos. 61/019,061 and 61/020,265 to protect other aspects of the PoNS device and related non-invasive neurostimulation techniques.

ANR holds an interest in the Patent Pending Rights pursuant to an exclusive license from the inventors. U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,258,790; and 10,328,263 are included in the exclusive license as the exclusive license agreement covers (i) U.S. Patent Application No. 12/348,301 (now U.S. Patent No. 8,849,407) and Provisional Application No. 61/019,061, (ii) any patents issuing therefrom and (iii) any patents claiming priority to U.S. Patent Application No. 12/348,301 or Provisional Application No. 61/019,061, which U.S. Patent Nos. 8,909,345; 9,020,612; 9,656,078; 9,597,501; 9,597,504; 9,656,069; 10,258,790; and 10,328,263 claim priority through such provisional application as well as through Provisional Application 61/020,265.

In addition, ANR has agreed that ownership of any improvements, enhancements or derivative works of the Patent Pending Rights that are developed by HMI or ANR shall be owned by HMI, provided that if HMI decides not to patent such improvements, ANR may choose to pursue patent rights independently. Pursuant to the Sublicense Agreement, HMI has agreed to pay ANR royalties equal to 4% of HMI's revenues collected from the sale of devices covered by the Patent Pending Rights and services related to the therapy or use of devices covered by the Patent Pending Rights in therapy services. The Sublicense Agreement provides that the sublicense granted by ANR to HMI, if in good standing, shall not be cancelled; limited or impaired in any way should there be a termination of the master license granted by the inventors to ANR, which was acknowledged by the inventors in the Sublicense Agreement. The Sublicense Agreement acknowledges the Reverse Merger (see "Our Corporate History—Acquisition of Helius Medical, Inc and Concurrent Financing" below) and adds us as a party to the agreement.

The license of the Patent Pending Rights is subject to the right of the government of the United States, which funded certain research relating to the development of the PoNS device, to a nonexclusive, non-transferable, irrevocable, paid up license to use the Patent Pending Rights for governmental purposes. In addition, HMI has granted a perpetual, royalty-free license to the Patent Pending Rights back to ANR for non-profit research and development activities, which do not compete with HMI's business and to produce and derive revenues from devices and services in connection with investigational uses of the PoNS device and related technology.

The license of the Patent Pending Rights is also subject to the terms of the CRADA. In the event that we are not willing or unable to commercialize the PoNS technology within four years from the expiration of the CRADA, the Company is required to transfer possession, ownership and sponsorship/holdership of the regulation application, regulatory correspondence and supporting regulatory information related technology to USAMRMC and grant the U.S. Government a non-exclusive, irrevocable license to any patent, copyright, data rights, proprietary information or regulatory information for the U.S. Government to commercialize the technology.

Company Owned Intellectual Property

As of January 11, 2021, we have filed 36 U.S. patent applications related to various technical and ornamental aspects of the PoNS device: 17 non-provisional patent applications that describe various technical features in the current version device and 19 design patent applications describing various ornamental designs. We are the sole assignee for these 36 U.S. patent filings. In addition to the first issued patent (U.S. Patent No. 9,072,889), the USPTO has issued 13 utility patents and 19 design patents as summarized in the table below:

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
14/558,768	12/3/2014	Issued	9,072,889	7/7/2015	Utility patent covering overall system design, including controller and mouthpiece
14/559,123	12/3/2014	Issued	9,272,133	3/1/2016	Utility patent covering strain relief mechanisms for the connection between the mouthpiece and the controller
14/558,787	12/3/2014	Issued	9,227,051	1/5/2016	Utility patent covering shape of the mouthpiece
14/558,789	12/3/2014	Issued	9,283,377	3/15/2016	Utility patent covering center of gravity of the mouthpiece
14/559,080	12/3/2014	Issued	9,415,209	8/16/2016	Utility patent covering structural support of the mouthpiece
14/559,105	12/3/2014	Issued	9,415,210	8/16/2016	Utility patent covering glue wells of the mouthpiece
14/727,100	6/1/2015	Issued	9,616,222	4/11/2017	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
14/558,775	12/3/2014	Issued	9,981,127	5/29/2018	Utility patent covering aspects of the controller
14/558,784	12/3/2014	Issued	9,789,306	10/17/2017	Utility patent covering authentication techniques
14/559,045	12/3/2014	Issued	9,993,640	6/12/2018	Utility patent covering the locators of the mouthpiece

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
14/559,118	12/3/2014	Issued	9,656,060	5/23/2017	Utility patent covering methods of manufacturing the mouthpiece
15/484,077	4/21/2017	Issued	10,258,790	4/16/2019	Utility application covering overall system design, including controller and mechanical details of the mouthpiece
15/602,055	9/5/2017	Issued	10,463,850	11/5/2019	Utility application covering methods of manufacturing the mouthpiece
16/005,624	6/11/2018	Issued	10,709,887	7/14/2020	Utility patent application covering methods of placing a mouthpiece in a patient's mouth prior to engaging in NINM
16/384,016	4/15/2019	Pending	N/A	N/A	Utility patent application covering overall system design, including controller and mechanical details of the mouthpiece, where controller and mouthpiece communicate wirelessly
16/376,595	4/5/2019	Pending	N/A	N/A	Utility patent application covering non-invasive neurostimulation of a subject's oral cavity or skin while the subject engages in a physical or cognitive exercise in order to enhance a subject's proficiency in the exercise
29/510,741	12/3/2014	Issued	D750264	2/23/2016	Design patent covering an alternative version of the current PoNS device (over-ear double boom design)
29/510,742	12/3/2014	Issued	D749746	2/16/2016	Design patent covering an alternative version of the current PoNS device (overhead minimal interference design)
29/510,743	12/3/2014	Issued	D752236	3/22/2016	Design patent covering system design used in the current PoNS device
29/510,745	12/3/2014	Issued	D750265	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,754	12/3/2014	Issued	D750794	3/1/2016	Design patent covering the controller used in the PoNS device
29/510,755	12/3/2014	Issued	D751215	3/8/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,746	12/3/2014	Issued	D750266	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,749	12/3/2014	Issued	D750268	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,747	12/3/2014	Issued	D751213	3/8/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,748	12/3/2014	Issued	D750267	2/23/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
29/510,750	12/3/2014	Issued	D753315	4/5/2016	Design patent covering mouthpiece used in the current PoNS device
29/510,751	12/3/2014	Issued	D751722	3/15/2016	Design patent covering an alternative controller not used in the current PoNS device

U.S. Patent Application No.	Application Filing Date	Status	U.S. Patent No.	Issue Date	Subject Matter
29/510,752	12/3/2014	Issued	D752766	3/29/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,753	12/3/2014	Issued	D753316	4/5/2016	Design patent covering an alternative controller not used in the current PoNS device
29/510,744	12/3/2014	Issued	D760397	6/28/2016	Design patent covering alternative system design used in the current PoNS device
29/510,756	12/3/2014	Issued	D759830	6/21/2016	Design patent covering alternative system design used in the current PoNS device
29/681,984	2/28/2019	Issued	D891084	7/28/2020	Design patent covering mouthpiece retainer case design used in the current PoNS device
29/681,990	2/28/2019	Issued	D894601	9/1/2020	Design patent covering carry case design used in the current PoNS device
29/682,001	2/28/2019	Pending	D907221	1/5/2021	Design patent covering alternative system design used in the current PoNS device

In addition to our U.S. patents, we have been granted 18 foreign utility patents (eight in Australia, five in Russia, two in Israel, two in Europe (validated in France, Germany, Italy, UK and Spain) and one in Eurasia, or EA, (validated in all eight Eurasian member-states), and 28 foreign design patents (three in Australia, seven in Canada, three in Russia, and 15 registered community designs in Europe), as detailed in the tables below.

Foreign Utility Patents

Australian Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
2015355211	6/4/2017	Issued	2015355211	11/16/2017	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
2015355212	6/4/2017	Issued	2015355212	12/21/2017	Utility patent covering center of gravity of the mouthpiece
2017218934	8/19/2017	Issued	2017218934	1/3/2018	Utility patent covering overall system design, including controller and mechanical details of the mouthpiece
2017276270	12/13/2017	Issued	2017276270	6/28/2018	Utility patent covering authentication techniques
2018204184	6/11/2018	Issued	2018204184	10/25/2018	Utility patent covering aspects of the controller
2017228517	9/11/2017	Issued	2017228517	1/24/2019	Utility application covering the shape of the mouthpiece
2018247259	10/11/2018	Issued	2018247259	11/28/2019	Utility patent covering overall system design, including controller and mouthpiece, and authentication techniques
2019200175	1/7/2019	Issued	2019200175	10/24/2019	Utility patent covering the locators of the mouthpiece

Eurasian Application No.	Application Filing Date	Status	Eurasian Patent No.	Issue Date	Subject Matter
201790009	1/10/2017	Issued	28551 (validated in 8 EA states)	11/30/2017	Utility patent covering methods for non-invasively aiding neurorehabilitation using intraoral stimulation in combination with an exercise regimen

European Application No.	Application Filing Date	Status	European Patent No.	Issue Date	Subject Matter
15813638.2	7/1/2019	Issued	3226962	7/3/2019	Utility application covering overall system design, including controller and mouthpiece
15812899.1	8/6/2019	Issued	3226961	8/7/2019	Utility application covering shape of the mouthpiece

Russian Application No.	Application Filing Date	Status	Russian Patent No.	Issue Date	Subject Matter
2017123125	6/1/2017	Issued	2649512	4/3/2018	Utility patent covering overall system design, including controller and mouthpiece
2017123041	6/1/2017	Issued	2652571	4/26/2016	Design patent covering the controller design currently used in the PoNS device
2018108570	3/12/2018	Issued	2665385	8/29/2018	Utility patent covering center of gravity of the mouthpiece
2018129619	8/14/2019	Issued	2686950	5/6/2019	Utility patent covering authentication techniques
2018112065	3/28/2018	Issued	2686044	4/23/2019	Utility patent covering center of gravity of the mouthpiece

Israeli Application No.	Application Filing Date	Status	Israeli Patent No.	Issue Date	Subject Matter
252649	6/4/2017	Issued	252649	12/21/2018	Utility patent covering center of gravity of the mouthpiece
252648	6/1/2017	Issued	252648	8/31/2019	Utility patent covering overall system design, including controller and mouthpiece

Foreign Design Patents

Russian Design Application No.	Application Filing Date	Status	Russian Patent No.	Issue Date	Subject Matter
2015501883	6/3/2015	Issued	98981	7/16/2016	Design patent covering the system design currently used in the PoNS device
2015501882	6/3/2015	Issued	99240	42598	Design patent covering the mouthpiece design currently used in the PoNS device
2015501881	6/3/2015	Issued	98947	7/16/2016	Design patent covering the controller design currently used in the PoNS device

Canadian Design Application No.	Application Filing Date	Status	Canadian Patent No.	Issue Date	Subject Matter
162676	6/2/2015	Issued	162676	2/29/2016	Design patent covering system design used in the current PoNS device
162672	6/2/2015	Issued	162672	2/29/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
162671	6/2/2015	Issued	162671	2/29/2016	Design patent covering an alternative mouthpiece not used in the current PoNS device
162674	6/2/2015	Issued	162674	2/29/2016	Design patent covering mouthpiece used in the current PoNS device
162675	6/2/2015	Issued	162675	2/29/2016	Design patent covering an alternative controller not used in the current PoNS device
162670	6/2/2015	Issued	162670	2/29/2016	Design patent covering the controller used in the PoNS device
162673	6/2/2015	Issued	162673	2/29/2016	Design patent covering system design used in the current PoNS device

EU Community Design Application No.	Application Filing Date	Status	EU Community Design Reg. No.	Issue Date	Subject Matter
002712026	6/3/2015	Issued	002712026-0001 -002712026-0007	9/4/2015	Design patents covering several aspects of the system design currently used in the PoNS device
006753877	8/23/2019	Issued	006753877-0001 - 006753877-0008	10/24/2019	Design patents covering the controller design used in the PoNS device

Australian Design Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
201914827	8/26/2019	Issued	201914827	10/8/2019	Design patent covering system design used in the PoNS device
201914900	8/28/2019	Issued	201914900	10/24/2019	Design patent covering the controller design used in the PoNS device
201914906	8/28/2019	Issued	201914906	10/23/2019	Design patent covering the mouthpiece design used in the PoNS device

Further, we have seven foreign utility patent applications that are currently pending: one application in Australia, and two applications in each of Canada, Europe, and Russia and three design patent applications that are currently pending in Russia:

Australian Application No.	Application Filing Date	Status	Australian Patent No.	Issue Date	Subject Matter
2019246836	10/9/2019	Pending	N/A	N/A	Utility patent application covering methods of placing a mouthpiece in a patient's mouth prior to engaging in NINM

Canadian Application No.	Application Filing Date	Status	Canadian Patent No.	Issue Date	Subject Matter
2969729	6/2/2017	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece, and authentication techniques
2969731	6/2/2017	Pending	N/A	N/A	Utility application covering various aspects of the mouthpiece such as shape, center of gravity, and the locators

European Application No.	Application Filing Date	Status	European Patent No.	Issue Date	Subject Matter
19183730.1	7/1/2019	Pending	N/A	N/A	Utility application covering overall system design, including controller and mouthpiece
19190373.1	8/6/2019	Pending	N/A	N/A	Utility patent application covering methods of placing a mouthpiece in a patient's mouth prior to engaging in NINM

Russian Application No.	Application Filing Date	Status	Russian Patent No.	Issue Date	Subject Matter
2019112637	4/25/2019	Pending	N/A	N/A	Utility patent application covering aspects of the controller
2019109970	4/4/2019	Pending	N/A	N/A	Utility patent application covering the locators of the mouthpiece
2019503625	8/28/2019	Pending	N/A	N/A	Design patent application covering the mouthpiece design used in the PoNS device
2019503624	8/28/2019	Pending	N/A	N/A	Design patent application covering the controller design used in the PoNS device
2019503623	8/28/2019	Pending	N/A	N/A	Design patent application covering the system design used in the PoNS device

Currently, we own rights in four trademarks: PoNS, Helius, Helius Medical, and Helius Medical Technologies. We own the rights to the PoNS mark by virtue of an assignment agreement having an effective date of October 27, 2014 and entered into with ANR and the inventors of the PoNS technology. We are also the owner of the rights in the Helius, Helius Medical, and Helius Medical Technologies marks.

We are the owner of the rights in PoNS, Helius and Helius Medical Technologies marks in Canada. We have also applied for the PoNS trademark in Europe, Russia, China, Australia, New Zealand and Israel. We have also applied for the Helius mark in the U.S., Australia and Canada, and the Helius Medical mark in the U.S.

Government Regulation

Our products under development and our operations are subject to significant government regulation. In the United States, our products are regulated as medical devices by the FDA and other federal, state, and local regulatory authorities. The following is a general description of the review and marketing authorization process of the FDA for medical devices.

FDA Regulation of Medical Devices

The FDA and other U.S. and foreign governmental agencies regulate, among other things, the following activities with respect to medical devices:

- design, development and manufacturing;

- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product storage and safety;
- marketing, sales and distribution;
- pre-market clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

In the United States, numerous laws and regulations govern all the processes by which medical devices are brought to market and marketed. These include the Food, Drug, and Cosmetic, or FD&C Act and the FDA's implementation of regulations, among others.

The FDA Review, Clearance and Approval Processes

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a premarket approval, or PMA, or approval of a de novo application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device.

Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's "general controls" for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to FDA's general controls, and any other "special controls" deemed necessary by FDA to ensure the safety and effectiveness of the device, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process, though certain Class II devices are exempt from this premarket review process. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to a legally marketed device, which in some cases may require submission of clinical data. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. If the FDA determines that the device, or its intended use, is not substantially equivalent to a legally marketed device, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous premarketing requirements.

Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device. The

safety and effectiveness of Class III devices cannot be assured solely by general or special controls. Submission and FDA approval of a premarket approval, or PMA, application is required before marketing of a Class III device can proceed. As with 510(k) submissions, unless subject to an exemption, PMA submissions are subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, typically including data from preclinical studies and human clinical trials.

Our PoNS device is regulated as a Class II medical device. We utilized the de novo classification procedures to seek U.S. marketing authorization for the PoNS device for gait deficit in MS, because there is no predicate cleared or approved by the FDA for commercial distribution and no existing classification decision by the FDA for such a device.

If the FDA requires us to go through a lengthier, more rigorous examination for the PoNS device for gait deficit in MS, introducing the product could be delayed or canceled, which could cause our commercial launch for the PoNS device for gait deficit in MS in the United States to be delayed or to not occur. In addition, the FDA may determine that the PoNS device requires the more costly, lengthy and uncertain PMA process. For example, if the FDA disagrees with our determination that the de novo classification procedures are the appropriate path to obtain marketing authorizations for the PoNS device in MS, the FDA may require us to submit a PMA application, which is generally more costly and uncertain and can take from one to three years, or longer, from the time the application is submitted to the FDA until an approval is obtained. Further, even with respect to those future products where a PMA may not be required, we cannot be certain that we will be able to obtain 510(k) clearances with respect to our PoNS device.

510(k) Clearance Process

To obtain 510(k) clearance for a medical device, an applicant must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A legally marketed predicate device may include a device that was legally marketed prior to May 28, 1976 for which a PMA is not required (known as a "pre-amendments device" based on the date of enactment of the Medical Device Amendments of 1976), a device that has been reclassified from Class III to Class II or Class I, or a device that was found substantially equivalent through the 510(k) process. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics, or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. A showing of substantial equivalence sometimes, but not always, requires clinical data.

Before the FDA will accept a 510(k) submission for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information before the FDA will proceed with additional review of the submission. Once the 510(k) submission is accepted for review, by regulation, the FDA has 90 days to review and issue a determination. As a practical matter, clearance often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a "letter to file" in which the manufacture documents the rationale for the change and why a new 510(k) is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

De novo Classification Process

If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the de novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

We utilized the de novo classification process to request our marketing authorization for the PoNS device for gait deficit in MS, and we plan to seek Class II classification. In order to be placed in Class II, the FDA would need reasonable assurance of safety and effectiveness of the PoNS device. Under Class II, general controls (e.g., premarket notification) and special controls (e.g., specific performance testing) would be applicable.

Obtaining FDA marketing authorization, de novo classification and clearance, or approval for medical devices is expensive and uncertain, generally takes several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA authorization for commercial distribution. Even if we were to obtain regulatory authorization, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

Clinical Trials

Clinical trials are typically required to support a PMA and are sometimes required to support a 510(k) or de novo submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping,

reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a ‘‘significant risk,’’ as defined by the FDA, to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. If the device is considered a “non-significant risk,” IDE submission to FDA is not required. Instead, only approval from the Institutional Review Board, or IRB, overseeing the investigation at each clinical trial site is required.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA’s regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and record keeping requirements.

Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a clinical trial is completed, there can be no assurance that the data generated during a clinical study will meet the safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval.

Pervasive and Continuing U.S. Food and Drug Administration Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of investigational products, or ‘‘off-label’’ uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the FTC and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that modification of promotional materials or subject a company to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Healthcare providers, physicians, and third party payers will play a primary role in the recommendation and use of any products for which we obtain marketing approval. Our future arrangements with third party payers, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any device for which we obtain marketing approval. In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. The applicable laws and regulations include the federal health care programs Anti-Kickback Statute (“AKS”) and the federal Civil False Claims Act.

The AKS makes it illegal for any person, including a device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, or order of a particular device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to ten years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

The Federal Civil False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,463 and $22,927 (adjusted annually for inflation) for each separate false claim and the potential for exclusion from participation in federal healthcare programs. Conduct that violates the False Claims Act also may implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal AKS also are deemed false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.

The manufacturing processes associated with medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, design history file, device history records, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Any failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on manufacturing operations and the recall or seizure of products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a company has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Health Canada

After a medical device has been approved for commercial use in Canada, there are a number of Health Canada requirements that must be adhered to including but not limited to the following:

- annual license renewals;
- labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit on the promotion of products for unapproved or "off-label" use and impose other restrictions on labeling;
- assessment of product modifications for significant changes that would require license amendments;
- post-market surveillance including medical device reporting, which requires manufacturers report to Health Canada if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- other post-approval restrictions or conditions.

European Union

We submitted an application for a CE Mark of the PoNS device with our UK based notified body in December 2018. In August 2019 we withdrew our application from the EU marketing process due to notified body activities being delayed by Brexit and the upcoming medical devices regulation changes. We have engaged G-MED NA as our notified body and will reconsider submitting to the EU when conditions stabilize. The successful completion of this review would result in marketing authorization for the sale of the PoNS device in the EU. Some EU member states have additional notification requirements that we expect to satisfy before we launch our PoNS Treatment in those member states. Once the PoNS device is placed into the EU market, post-market requirements apply including but not limited to:

- ensuring that the labeling promotes only approved use(s) of the device;
- assessment of product modifications for significant changes may require license amendments;
- post-market surveillance including vigilance reporting, which requires manufacturers report to authorities if our PoNS device caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- other post-approval restrictions or conditions.

Australia

We submitted our application for marketing authorization to the TGA during the third quarter of 2019. We supplemented our submission with additional data based on questions supplied to date and provided responses to additional questions during the third quarter of 2020. We are currently awaiting additional feedback from the TGA on our application.

Third-Party Payer Coverage and Reimbursement

Significant uncertainty exists as to whether coverage and reimbursement of the PoNS Treatment will develop; but we intend to seek reimbursement through private or governmental third-party payers in the future. In both the United States and foreign markets, our ability to commercialize the PoNS device successfully, and to attract commercialization partners for the PoNS device, depends in part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a

federally funded program managed by the CMS, through local contractors that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured, and it is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations or other guidelines that govern its individual program. Each payer, whether governmental or private, has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payers often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. On January 12, 2021, the CMS stated that it is finalizing a new Medicare coverage pathway, Medicare Coverage of Innovative Technology, or "MCIT," for FDA-designated breakthrough medical devices. The MCIT rule will provide national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices and coverage would last for four years. The competitive position of the PoNS device will depend, in part, upon the extent of coverage and adequate reimbursement for such product and for the procedures in which such product is used. Prices at which we or our customers seek reimbursement for the PoNS device can be subject to challenge, reduction or denial by the government and other payers.

In the event we do receive approval for third-party or government reimbursement for our product, the marketability of such product may suffer if the government and commercial third-party payers fail to provide adequate coverage and reimbursement. An emphasis on cost containment measures in the United States has increased and we expect it will continue. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained if and when we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

State and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for our product candidate for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In addition, in some foreign countries, the proposed pricing for a medical device must be approved before it may be lawfully marketed. The requirements governing medical device pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medical devices for which their national health insurance systems provide reimbursement and to control the prices of medical devices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our medical device to other available therapies in order to obtain or maintain reimbursement or pricing approval. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be priced significantly lower. Publication of discounts by third-party payers or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our medical device is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our medical devices in those countries would be negatively affected.

Data Privacy and Security Laws; Breaches

Medical device companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in

connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the U.S. Department of Health and Human Services, or HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, or PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the FTC failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Personally identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to PHI, than HIPAA, and many of which differ from each other, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Additionally, many of the more ambiguous provisions of the CCPA have yet to be fully interpreted and applied, and numerous amendments have been proposed and are working their way through legislature. Consequently, the CCPA currently presents many compliance questions that remain unresolved. The CCPA may increase our compliance costs and potential liability. In addition to the CCPA, numerous other states' legislatures are considering similar laws that will require ongoing compliance efforts and investment.

In the European Union, as of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation, or GDPR, replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

Our Corporate History Highlights

Formation and Arrangement with Boomerang Oil, Inc.

We were originally incorporated in British Columbia, Canada on March 13, 2014 under the British Columbia Business Corporations Act, or the BCBCA, as "0996445 B.C. Ltd." On March 25, 2014, and amended on April 8, 2014, we entered into an arrangement agreement with Boomerang Oil, Inc. (formerly known as 0922327 B.C. Ltd.) and 0995162 B.C. Ltd. to reorganize the business structure of such three entities in such a manner which would allow Boomerang Oil, Inc. to spin us out to become an independent entity that is a reporting

issuer in Canada and for us to complete a reverse take-over of 0995162 B.C. Ltd. As a result of the arrangement agreement, we became a reporting issuer in the provinces of British Columbia and Alberta. In addition, the arrangement resulted in 0995162 B.C. Ltd. becoming our wholly owned subsidiary. The assets of 0995162 B.C. Ltd. consisted of cash and 0995162 B.C. Ltd.'s interest in a letter agreement pursuant to which it had agreed to acquire all of the outstanding shares of HMI, a Delaware corporation, and to seek a listing on a recognized stock exchange.

Reincorporation in Wyoming

On May 23, 2014, we changed our name to "Helius Medical Technologies, Inc." and filed articles of continuation with the Wyoming Secretary of State office to reincorporate from being a corporation governed by the BCBCA to a corporation governed by the Wyoming Business Corporation Act.

Acquisition of NeuroHabilitation Corporation and Concurrent Financing

On June 13, 2014, we completed the acquisition of NeuroHabilitation Corporation, or NHC, by way of an agreement and plan of merger. We refer to this transaction as the Reverse Merger. Pursuant to the agreement and plan of merger, HMT Mergersub, Inc., our wholly owned subsidiary, merged with and into NHC with NHC as the surviving corporation. In connection with the Reverse Merger, we issued an aggregate of 201,714 shares of our common stock to the former shareholders of HMI. The Reverse Merger was deemed to be a capital transaction in substance and recorded as a reverse recapitalization of NHC whereby NHC is deemed to be the continuing, surviving entity for accounting purposes, but through reorganization, has deemed to have adopted the capital structure of Helius. On December 21, 2018, NHC changed its name to Helius Medical, Inc.

In connection with the Reverse Merger, we completed a non-brokered private placement financing of $7.02 million (CAD$7.62 million) by issuing 87,085 subscription receipts. Pursuant to its terms, each subscription receipt automatically converted into one unit upon satisfaction of certain escrow release conditions, which had been satisfied. Each unit consisted of one share of our common stock and one-half of one share purchase warrant with each whole warrant being exercisable at CAD$175.00 per share for a period of two years.

Change in Functional Currency

Prior to April 1, 2018, our functional currency was the Canadian dollar, or CAD$. We re-assessed our functional currency and as of April 1, 2018, our functional currency changed from the CAD$ to the U.S. dollar based on management's analysis of changes in the primary economic environment in which we operate. The change in functional currency was accounted for prospectively from April 1, 2018 and financial statements prior to and including the period ended March 31, 2018 were not restated for the change in functional currency.

Reincorporation in Delaware

On June 28, 2018, at our 2018 Annual Meeting of Shareholders, our shareholders approved our reincorporation from the state of Wyoming to the state of Delaware. On July 20, 2018, we completed the reincorporation to the state of Delaware.

Formation of Helius NeuroRehab Inc.

In January 2019, we formed Helius NeuroRehab, Inc., or HNR, a Delaware corporation, which is a wholly owned subsidiary of Helius Medical Technologies, Inc. to operate a clinic focusing on the delivery of PoNS Treatment to patients with balance and gait disorders if and when FDA clearance is received.

Formation of Helius Canada Acquisition Ltd.

On October 10, 2019, we formed Helius Canada Acquisition Ltd., or HCA, a company incorporated under the federal laws of Canada, which is a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc., or HMC, a company incorporated under the federal laws of Canada, which acquired Heuro Canada, Inc., or Heuro, from Health Tech Connex Inc., or HTC, on October 30, 2019 (see Note 2 to our audited consolidated financial statements included elsewhere in this prospectus).

Acquisition of Heuro Canada Inc.

On October 30, 2019, we acquired Heuro, a company incorporated under the federal laws of Canada, which is a wholly owned subsidiary of HCA, from HTC (see Note 2 to our audited consolidated financial statements included elsewhere in this prospectus).

Listing of our Common Stock

Following our Reverse Merger, we obtained approval of the listing of our common stock on the Canadian Securities Exchange, or CSE, on June 23, 2014. On April 18, 2016, our common stock was listed on the TSX under the symbol "HSM." At the same time, we delisted our common stock from the CSE. The Company's common stock also began trading on the OTC Markets, or OTCQB, under the ticker symbol "HSDT" on February 10, 2015. On April 11, 2018, our common stock began trading on the Nasdaq Capital Market under the ticker symbol "HSDT" and ceased to trade on the OTCBQ.

On March 23, 2020, the Company received notice from the Staff of Nasdaq that the bid price for the Company's common stock had closed below $1.00 per share for the prior 30-consecutive business day period and that the Company had been granted a 180-day grace period, through September 21, 2020, to regain compliance with Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Rule"). Thereafter, on April 17, 2020, the Company received an additional notice from the Staff indicating that Nasdaq had temporarily stayed enforcement of the Minimum Bid Price Rule through June 30, 2020 and, accordingly, the 180-day grace period applicable to the Company would not expire until December 3, 2020.

On December 4, 2020, the Company received notice from the Staff indicating that the Company was not eligible for an additional 180 day extension to meet the Minimum Bid Price Rule. As a result, the Staff determined that the Company's securities would be subject to delisting unless the Company timely requests a hearing before the Panel. The Company timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concludes and any extension granted by the Panel expires. On January 15, 2021, the Company received notice from the Staff that the bid price deficiency of the Company had been cured, and that the Company was in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

Reverse Stock Splits

Effective after the close of business on January 22, 2018, we completed a 1-for-5 reverse stock split of our common stock. All share and per share amounts in this prospectus have been reflected on a post-split basis. At a special meeting of our stockholders on December 28, 2020, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-5 to 1-for-35 to be determined at the discretion of our Board of Directors, whereby each outstanding 5 to 35 shares would be combined, converted and changed into 1 share of our common stock, to enable the Company to comply with Nasdaq's continued listing requirements. Following such meeting, our board of directors approved a final reverse stock split ratio of 1-for-35. The reverse stock split did not change the par value of our stock or the authorized number of common or preferred shares. All share and per share amounts for all periods presented in this prospectus and the registration statement of which it forms a part have been retroactively adjusted for the reverse stock split effected on December 31, 2020.

Corporate Information

Our principal executive offices are located at 642 Newtown Yardley Road, Suite 100, Newtown, PA 18940 and our telephone number is 215-944-6100. We maintain a corporate website at www.heliusmedical.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as its reasonably practicable after we electronically file such material with, or furnish such material to the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this prospectus or the registration statement of which it forms a part. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov.

Human Capital Resources

As of September 30, 2020, we had 18 full time employees, no part time employees and 1 full time consultant and 6 part time consultants. Given the change in our United States regulatory timeline in 2019, we prioritized our resources to support our resubmission to the FDA and commercialization efforts in Canada and reduced our workforce by over 30% to scale back the staff that was hired to prepare for our commercial launch in the United States while maintaining the necessary distribution, regulatory and quality system infrastructure to support our commercial launch in Canada.

Properties

Our head office is located at 642 Newtown-Yardley Road, Suite 100, Newtown, PA 18940, with 2,500 square feet of lease office space. In May 2020, the Company terminated its lease and entered into a new lease (the "Lease Amendment") for a smaller footprint of the current office space in Newtown, Pennsylvania. Lease payments under the original contract were made through December 2020. In January 2021, we signed a Lease Amendment extending our current lease term from July 1, 2020 through September 30, 2021, which may be extended on a month-to-month basis. Monthly rent plus utilities is approximately $5 thousand per month with a 3% annual increase. We believe our current facilities are adequate for our needs.

Legal Proceedings

From time to time, we are subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

MANAGEMENT

Directors, Executive Officers and Corporate Governance

The following table provides information as to each person who is, as of the filing hereof, a director and/or executive officer of the Company:

Name	Age	Position
Dane C. Andreeff	55	Interim President and Chief Executive Officer and Director
Joyce LaViscount	58	Chief Financial Officer and Chief Operating Officer
Jonathan Sackier	63	Chief Medical Officer
Edward M. Straw	81	Director
Mitchell E. Tyler	67	Director
Blane Walter	50	Chairman of the Board
Jeffrey S. Mathiesen	60	Director

No Family Relationships

There is no family relationship between any director and executive officer or among any directors or executive officers.

Business Experience and Background of Directors and Executive Officers

Dane C. Andreeff

Mr. Andreeff has served as our Interim President and Chief Executive Officer since August 2020 and as a member of our Board of Directors since August 2017. Mr. Andreeff is the General Partner and Portfolio Manager at Maple Leaf Partners, LP, which owns approximately 6.0% of our outstanding common stock. Maple Leaf Partners, LP is a hedge fund founded by Mr. Andreeff, where he has been employed since 1996. In 2003, the fund was seeded by Julian Robertson's Tiger Management and later grew to over $2 billion in assets under management. Mr. Andreeff also serves as a member of the board of directors of TraceSecurity, LLC, HDL Therapeutics, Inc. and Myocardial Solutions, Ltd. Mr. Andreeff received his Bachelor's degree in Economics from the University of Texas at Arlington in 1989 and his Master's degree in Economics from the University of Texas at Arlington in 1991. The Board believes that Mr. Andreeff's extensive experience in the investment industry and capital markets and significant experience advising other companies as a board member, including multiple companies in the healthcare sector, make him a valuable member of the Board.

Joyce LaViscount

Ms. LaViscount has served as our Chief Financial Officer and Chief Operating Officer since October 2015, and she previously served as a member of our Board of Directors from March 2015 to December 2015. Prior to joining Helius, Ms. LaViscount served as chief operating officer and chief financial officer of MM Health Solutions, formerly MediMedia Health, from July 2012 to August 2015. Ms. LaViscount concurrently served as the chief financial officer of MediMedia Pharmaceutical Solutions from January 2014 to February 2015. Previously, Ms. LaViscount served as executive director/group controller North America of Aptalis Pharmaceuticals from February 2011 to July 2012. Ms. LaViscount is a Certified Public Accountant. She received a B.A. in business with a concentration in accounting from Franklin and Marshall College in 1984.

Jonathan Sackier

Dr. Sackier has served as our Chief Medical Officer since December 2014. He has also served as a Visiting Professor of Surgery at the Nuffield Department of Surgical Sciences at Oxford University since 2014. From 2005 to 2014, Dr. Sackier was a Visiting Professor of Surgery at the University of Virginia and prior to that

served as a Clinical Professor at the George Washington University. Dr. Sackier has served as a director of Kypha, Inc. since July 2014, Clinvue LLC since July 2010, Brandon Medical since May 2013 and SoundPipe Therapeutics since September 2013. He previously served as a director of HemoShear Therapeutics, LLC from 2008 to 2015. He is a trustee of First Star and previously chaired the Larry King Cardiac Foundation Board of Governors. A keen pilot, Jonathan advises the Aircraft Owners & Pilots Association on medical issues germane to pilots and authors the "Fly Well" column in the association's *Pilot* magazine.

Edward M. Straw

Vice Admiral Edward M. Straw, USN, (Retired) has served as a member of our Board of Directors since November 2014. He founded Osprey Venture Partners in 2011, a firm that mentors young entrepreneurs seeking investment capital and assists with business development and serves as the managing director. Previously he was president, global operations of The Estée Lauder Companies from 2000 to 2005, senior vice president global operations of the Compaq Computer Corporation from 1998 to 2000, and president of Ryder Integrated Logistics from 1996 to 1998. Prior to joining the private sector, he had a distinguished 35-year career in the U.S. Navy and retired as a three-star admiral. During his military service, Vice Admiral Straw was Director (CEO) of the Defense Logistics Agency, the largest military logistics command supporting the American armed forces. He is a member of the Defense Science Board, chairman of Odyssey Logistics and currently sits on the boards of The Boston Consulting Federal Group, Academy Securities and Lenitiv Scientific. He is a former board member of Eddie Bauer, MeadWestvaco, Ply Gem Industries and Panther Logistics. Vice Admiral Straw received a B.S. from the United States Naval Academy, an MBA from The George Washington University, and is a graduate of the National War College. Our Board of Directors believes that Vice Admiral Straw is qualified to serve as a director based on his extensive leadership experience in both the private sector and the U.S. military.

Mitchell E. Tyler

Mr. Tyler has served as a member of our Board of Directors since June 2014. Mr. Tyler is a co-inventor of the PoNS device and is co-owner and clinical director of Advanced NeuroRehabilitation LLC, a position he has held since 2009. Mr. Tyler retired in 2019 after 32 years at the University of Wisconsin as emeritus Senior Lecturer in Biomedical Engineering and Researcher in Rehabilitation Medicine. From 1998 through 2017, Mr. Tyler also served as the clinical director of the Tactile Communication and NeuroRehabilitation Laboratory. He received his M.S. in Bioengineering from University of California, Berkeley in 1985 and is currently working on his Ph.D. in Biomedical Engineering at the University of Wisconsin–Madison. Mr. Tyler is a registered professional engineer in Wisconsin. Our Board of Directors believes that Mr. Tyler is qualified to serve as a director based on his extensive knowledge of PoNS treatment and his research and development experience in the medical device industry.

Blane Walter

Mr. Walter has served as a member of our Board of Directors since December 2015 and as Chairman of the Board since August 2020. Mr. Walter is a partner at Talisman Capital Partners, a position he has held since 2011. In 1999, Mr. Walter founded inChord Communications, Inc., a global private healthcare communications company, which was acquired by inVentiv Health in 2005. Mr. Walter joined inVentiv Health as president of the Communications division in 2005 and was named Chief Executive Officer in 2008 and served in that capacity until leading the sale of the company to Thomas H. Lee Partners in 2010. Following the buyout, Mr. Walter served as vice chairman of inVentiv Group, a holding company which survived the buyout, from 2011 to August 2017. Mr. Walter received a B.S. in marketing and finance from Boston College in 1993. Our Board of Directors believes that Mr. Walter is qualified to serve as director based on his background in the healthcare and pharmaceutical industries.

Jeffrey S. Mathiesen

Mr. Mathiesen has served as a member of our Board of Directors since June 2020. Additionally, Mr. Mathiesen has served as Vice Chair and Lead Independent Director since March 2020 and as Director and Audit Committee Chair, since 2015, of Panbela Therapeutics, Inc. (Nasdaq: PBLA), a publicly traded biopharmaceutical company developing therapies for pancreatic diseases. Mr. Mathiesen has also served as Director and Audit Committee Chair of NeuroOne Medical Technologies Corporation (OTCQB: NMTC), a publicly traded medical technology company providing neuromodulation continuous EEG monitoring and treatment solutions for patients suffering from epilepsy and other nerve related disorders, since 2017, and eNeura, Inc., a privately held medical technology company providing therapy for both acute treatment and prevention of migraine, from 2018 to 2020. Mr. Mathiesen served as Advisor to the CEO of Teewinot Life Sciences Corporation, a privately held global leader in the biosynthetic development and production of cannabinoids and their derivatives for consumer and pharmaceutical products, from October 2019 to December 2019, and served as Chief Financial Officer from March 2019 to October 2019. Mr. Mathiesen previously served as Chief Financial Officer of Gemphire Therapeutics Inc., which was acquired by NeuroBo Pharmaceuticals, Inc. (NASDAQ: NRBO) in January 2020, a publicly-held clinical-stage biopharmaceutical company developing therapies for patients with cardiometabolic disorders, from 2015 to 2018, and as Chief Financial Officer of Sunshine Heart, Inc. (NASDAQ: CHFS), a publicly-held early-stage medical device company, from 2011 to 2015. Mr. Mathiesen received a B.S. in Accounting from the University of South Dakota and is a Certified Public Accountant. Our Board believes that Mr. Mathiesen is qualified to serve as director based on his background in a broad range of responsibilities in financial and operational roles, including manufacturing, quality and procurement, in addition to traditional CFO roles in organizations with operations in North America, Europe, Southeast Asia and Australia.

Director Independence

The Board reviews its composition annually, including the determination of the independence of our directors. Our Board consults with the Company's counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of the TSX and Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, the Board has affirmatively determined that all of the Company's directors, other than Messrs. Andreeff and Tyler, are independent under the standards set forth in applicable TSX and Nasdaq listing standards. In making those independence determinations, the Board took into account certain relationships and transactions that occurred in the ordinary course of business between the Company and entities with which some of its directors are or have been affiliated. The Board considered all relationships and transactions that occurred during any 12-month period within the last three fiscal years. The Board determined that the relationships would not interfere with their exercise of independent judgment in carrying out their responsibilities as directors.

Board Leadership Structure

The Company's Board of Directors is currently chaired by Blane Walter, an independent member of the Board.

The Board does not have a formal policy with respect to the separation of the offices of Chief Executive Officer and chairman of the Board. It is the Board's view that rather than having a formal policy, the Board, upon consideration of all relevant factors and circumstances, will determine, as and when appropriate, whether it is in the best interests of the Company and its stockholders for such offices to be separate or combined.

The Board currently believes that, by separating the positions of Chair of the Board and Chief Executive Officer, the Board can provide significant leadership to management and strong oversight of key opportunities

and risks impacting the Company. The Board may reconsider its leadership structure in connection with the appointment of a successor Chief Executive Officer to replace Mr. Andreeff, who is currently acting as Interim President and Chief Executive Officer.

Role of the Board in Risk Oversight

The Board plays an active role in overseeing management of our risks. The Board regularly reviews information regarding our credit, liquidity and operations, as well as the risks associated with each. The Audit Committee of the Board is responsible for overseeing the management of financial risks. The Compensation Committee also is responsible for overseeing the management of risks relating to our executive compensation policies and arrangements, and for managing risks relating to our director compensation policies and arrangements and reviewing the independence of the Board and other corporate governance matters.

Meetings of the Board of Directors

The Board of Directors met 11 times during 2020. Each current Board member who served as a director in 2020 attended 75% or more of the aggregate number of meetings of the Board and of the committees on which he served, held during the portion of the last fiscal year for which he was a director or committee member.

Information Regarding Committees of the Board of Directors

The Board has three committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The following table provides current committee membership:

Name	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Jeffrey S. Mathiesen	X*	X	
Edward M. Straw	X	X*	X
Blane Walter	X	X	X*

* Committee Chairperson

Below is a description of each committee of the Board of Directors. Each of the committees has authority to engage legal counsel or other experts or consultants, as it deems appropriate to carry out its responsibilities.

Audit Committee

The Audit Committee of the Board of Directors was established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act, to oversee the Company's corporate accounting and financial reporting processes and audits of its financial statements. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the performance of and assesses the qualifications of the independent auditors; determines and approves the engagement of the independent auditors; determines whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors; reviews and approves the retention of the independent auditors to perform any proposed permissible non-audit services; monitors the rotation of partners of the independent auditors on the Company's audit engagement team as required by law; reviews and approves or rejects transactions between the Company and any related persons; confers with management and the independent auditors regarding the scope, adequacy and effectiveness of internal control over financial reporting; establishes procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; and meets to review the Company's annual audited financial

statements and quarterly financial statements with management and the independent auditor, including a review of the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

The Audit Committee met four times during 2020. The Board has adopted a written Audit Committee charter that is available to stockholders on the Company's website at www.heliusmedical.com.

The Board of Directors reviews the Nasdaq and TSX listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of the Company's Audit Committee are independent.

The Board of Directors has also determined that Mr. Mathiesen qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made a qualitative assessment of Mr. Mathiesen's level of knowledge and experience based on a number of factors, including his formal education and experience as a chief financial officer for public reporting companies.

Compensation Committee

The Compensation Committee was established in March 2018. All members of the Company's Compensation Committee are independent (as independence is currently defined in Rule 5605(d)(2) of Nasdaq listing standards and TSX independence rules). The Compensation Committee met three times during 2020. The Board has adopted a written Compensation Committee charter that is available to stockholders on the Company's website at www.heliusmedical.com.

The Compensation Committee of the Board of Directors acts on behalf of the Board to review, recommend for adoption and oversee the Company's compensation strategy, policies, plans and programs, including establishing corporate and individual performance objectives relevant to the compensation of the Company's executive officers and other senior management and evaluation of performance in light of these stated objectives; reviewing and recommending to the Board for approval the compensation and other terms of employment or service, including severance and change-in-control arrangements, of the Company's Chief Executive Officer, the other executive officers and the directors; and administering the Company's equity compensation plans, pension and profit-sharing plans, deferred compensation plans and other similar plans and programs.

Compensation Determination: Processes and Procedures

The Compensation Committee will meet at least annually and with greater frequency if necessary and appropriate. The agenda for each meeting will be developed by the Chair of the Compensation Committee, in consultation with legal counsel or other advisers or consultants it deems necessary and appropriate. The Compensation Committee will meet regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the Compensation Committee to make presentations, to provide financial or other background information or advice or to otherwise participate in Compensation Committee meetings. The Chief Executive Officer may not participate in, or be present during, any deliberations or determinations of the Compensation Committee regarding his compensation or individual performance objectives. The charter of the Compensation Committee grants the Compensation Committee full access to all books, records, facilities and personnel of the Company. In addition, under the charter, the Compensation Committee has the authority to obtain, at the expense of the Company, advice and assistance from compensation consultants and internal and external legal, accounting or other advisors and other external resources that the Compensation Committee considers necessary or appropriate in the performance of its duties. The Compensation Committee has direct responsibility for the oversight of the work of any consultants or advisers engaged for the purpose of advising the Committee. In particular, the Compensation Committee has the sole authority to retain, in its sole discretion, compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant's reasonable fees and other retention terms. Under the charter, the Compensation Committee may select, or receive

advice from, a compensation consultant, legal counsel or other adviser to the Compensation Committee, other than in-house legal counsel and certain other types of advisers, only after taking into consideration six factors, prescribed by the SEC and Nasdaq, that bear upon the adviser's independence; however, there is no requirement that any adviser be independent.

Prior to the establishment of a formal compensation committee in March 2018, the non-employee directors of the Board performed the duties of a compensation committee and met at least four times per year, regularly in executive session, to discuss compensation. The non-employee directors invited management and other employees, outside advisors and/or consultants to join its meetings as appropriate to provide advice and background information. The Chief Executive Officer did not participate in, and was not present during, any deliberations or determinations of the non-employee directors regarding his compensation or individual performance objectives.

In fiscal 2020, the Board delegated authority to the Chief Executive Officer to grant, without any further action required by the Compensation Committee, equity awards to employees and consultants who are not officers of the Company. The purpose of this delegation of authority is to enhance the flexibility of option administration within the Company and to facilitate the timely grant of options to non-management employees, particularly new employees, within specified limits approved by the Board. Typically, as part of its oversight function, the Compensation Committee will review on a quarterly basis the list of grants made the Chief Executive Officer.

Historically, the non-employee directors and, since its establishment in 2018, the Compensation Committee, have made most of the significant adjustments to annual compensation, determined bonus and equity awards and established new performance objectives at one or more meetings held during the first quarter of the year. Generally, the process comprises two related elements: the determination of compensation levels and the establishment of performance objectives for the current year. For executives other than the Chief Executive Officer, the Compensation Committee solicits and considers evaluations and recommendations submitted to the Committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the Compensation Committee, which determines any adjustments to his compensation as well as awards to be granted. The Chief Executive Officer may not be present during these discussions. For all executives and directors as part of its deliberations, the Compensation Committee may review and consider, as appropriate, materials such as financial reports and projections, operational data, tax and accounting information, tally sheets that set forth the total compensation that may become payable to executives in various hypothetical scenarios, executive and director stock ownership information, company stock performance data, analyses of historical executive compensation levels and current Company-wide compensation levels and recommendations of the Company's compensation consultant, including analyses of executive and director compensation paid at other companies identified by the consultant.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee was established in March 2018. All members of the Nominating and Corporate Governance Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the Nasdaq listing standards and in the TSX Company Manual). The Nominating and Corporate Governance Committee met two times during 2020. The Board has adopted a written Nominating and Corporate Governance Committee charter that is available to stockholders on the Company's website at www.heliusmedical.com.

The Nominating and Corporate Governance Committee of the Board of Directors is responsible for identifying, reviewing and evaluating candidates to serve as directors of the Company (consistent with criteria approved by the Board), reviewing and evaluating incumbent directors, selecting or recommending to the Board for selection candidates for election to the Board of Directors, making recommendations to the Board regarding the membership of the committees of the Board, assessing the performance of management and the Board, and developing a set of corporate governance principles for the Company. Prior to the establishment of a formal nominating and governance committee in March 2018, the Board performed such duties as it did not believe a formal committee was necessary or cost efficient for a company of our size.

Generally, director nominees are identified and suggested by our directors or management using their business networks. The Nominating and Corporate Governance Committee also intends to consider director nominees put forward by stockholders. Our Amended and Restated Bylaws contain provisions that address the process by which a stockholder may nominate an individual to stand for election to the Board at the annual meeting. Stockholders may recommend individuals to our Board for consideration as potential director candidates by submitting the names of the recommended individuals, together with appropriate biographical information and background materials, to the Board at Helius Medical Technologies, Inc., 642 Newtown Yardley Road, Suite 100, Newtown, Pennsylvania 18940, Attention: Chairman of the Board. Such nomination must satisfy the notice, information and consent requirements set forth in our Amended and Restated Bylaws. The Board does not intend to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder.

The Nominating and Corporate Governance Committee does not have any specific minimum qualifications that director nominees must have in order to be considered to serve on the Board. However, the Nominating and Corporate Governance Committee does take into consideration areas of expertise that director nominees may be able to offer, including professional experience, knowledge, abilities and industry knowledge or expertise. The Nominating and Corporate Governance Committee also considers their potential contribution to the overall composition and diversity of the Board.

The Nominating and Corporate Governance Committee will conduct the appropriate and necessary inquiries (as determined by the Committee) with respect to the backgrounds and qualifications of any potential nominees, without regard to whether a potential nominee has been recommended by our stockholders, and, upon consideration of all relevant factors and circumstances, approves the slate of director nominees to be nominated for election at our annual meeting of stockholders.

The Nominating and Corporate Governance Committee considers potential nominees without regard to gender, race, color, creed, religion, national origin, age, sexual orientation or disability. In general, the Company seeks a Board that includes a diversity of perspectives and includes individuals that possess backgrounds, skills, expertise and attributes that allow them to function collaboratively and effectively together in their oversight of the Company.

Non-Employee Director Compensation

We adopted a non-employee director compensation policy, effective as of June 10, 2020, pursuant to which the Chairs of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee will receive an annual retainer of $10,000, $5,000 and $2,500, respectively, and our non-employee directors will receive board compensation in the form of an annual retainer equal to $20,000 delivered in options to purchase shares of our common stock, which vest in 12 equal monthly amounts. We also reimburse non-employee directors for reasonable expenses incurred in connection with attending Board and committee meetings.

The following table shows certain information with respect to the compensation of all non-employee directors of the Company for the fiscal year ended December 31, 2020. As named executive officers of the Company for 2020, compensation paid to Mr. Andreeff, our Interim President and Chief Executive Officer, and Mr. Deschamps, our former President and Chief Executive Officer, for the 2019 and 2020 fiscal years is fully reflected under"—Summary Compensation Table for 2020" below.

Name	Fees earned or paid in cash ($)	Option Awards ($) (5)	Total ($)
Jeffrey Mathiesen (1)	5,000	20,000	25,000
Mitchell E. Tyler (2)	0	20,000	20,000
Edward M. Straw (3)	1,250	20,000	21,250
Blane Walter (4)	1,250	20,000	21,250

(1) Mr. Mathiesen held 1,749 shares of common stock underlying option grants at December 31, 2020.
(2) Mr. Tyler held 3,011 shares of common stock underlying option grants at December 31, 2020.
(3) Vice Admiral (Retired) Straw held 3,825 shares of common stock underlying option grants at December 31, 2020.
(4) Mr. Walter held 3,004 shares of common stock underlying option grants at December 31, 2020.
(5) The amounts reflect the full grant date fair value for awards granted during the fiscal year ended December 31, 2020. The grant date fair value was computed in accordance with ASC Topic 718, Compensation—Stock Compensation. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the director will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note 4 to our audited financial statements included herein.

EXECUTIVE COMPENSATION

The following tables and accompanying narrative disclosure discuss the compensation awarded to, earned by, or paid to:

- Dane C. Andreeff, our Interim President and Chief Executive Officer;
- Phillippe Deschamps, our former Chief Executive Officer;
- Joyce LaViscount, our Chief Financial Officer and Chief Operating Officer; and
- Jonathan Sackier, our Chief Medical Officer.

We refer to these four current or former executive officers as the "named executive officers."

Summary Compensation Table for 2020

The following table presents summary information regarding the total compensation for services rendered in all capacities that was earned by our named executive officers during the fiscal years ended December 31, 2020 and 2019.

Name and Principal Position	Year	Salary ($) (1)	Option Awards ($) (2)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Dane C. Andreeff	2020	—	20,000	—	2,500	22,500
Interim President and Chief Executive Officer(3)	2019	—	79,144	—	—	79,144
Philippe Deschamps	2020	285,339	—	—	501,588 (5)	786,927
Former Chief Executive Officer(4)	2019	492,353	739,776	—	12,373(6)	1,244,502
Joyce LaViscount	2020	387,080	24,340	—(7)	1,220 (8)	412,640
Chief Financial Officer and Chief Operating Officer	2019	381,955	642,705	—	8,371(6)	1,033,031
Jonathan Sackier	2020	200,000	25,739	—(7)	1,650(8)	227,389
Chief Medical Officer	2019	336,553	462,360	—	—	798,913

(1) The amounts reported for 2020 and 2019 include the value of stock awards granted in 2020 to Mr. Deschamps 1,759 shares with a value of $31,915), and to Ms. LaViscount (2,155 shares with a value of $38,292), and in 2019 to Mr. Deschamps (376 shares with a value of $7,961) and Ms. LaViscount (258 shares with a value of $5,457), in each case, in lieu of base salary forgone at the election of such named executive officers commencing with the pay period ending December 13, 2019 as described in the last paragraph under "Narrative Disclosure to Summary Compensation Table—Equity-Based Awards". Mr. Deschamps' and Ms. LaViscount's elections to receive restricted stock awards in lieu of cash salary compensation were effective beginning with the December 13, 2019 payroll date and remained in place until May 11, 2020 for Mr. Deschamps and August 11, 2020 for Ms. LaViscount.

(2) The amounts reflect the full grant date fair value for awards granted during the indicated year. The grant date fair value was computed in accordance with ASC Topic 718, Compensation—Stock Compensation. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the executive will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note 4 to our audited financial statements included herein.

(3) Mr. Andreeff has been employed as Interim President and Chief Executive Officer of the Company since August 23, 2020. Prior to his appointment as Interim President and Chief Executive Officer, Mr. Andreeff was a non-employee director. Mr. Andreeff has elected to take no additional compensation in return for his service as Interim President and Chief Executive Officer. The amounts in the "Option Awards" and "All Other Compensation" columns for 2020 include an equity grant and cash compensation, respectively, that Mr. Andreeff received while serving as a non-employee director.

(4) Mr. Deschamps stepped down from his roles as President and Chief Executive Officer and director effective August 23, 2020 upon mutual agreement with the Board.
(5) Amounts reported for 2020 reflect that Mr. Deschamps' employment with the Company ended as of August 23, 2020. In addition to group life insurance premiums, "All Other Compensation" for 2020 includes a $501,000 severance payment to Mr. Deschamps, payable in equal monthly installments during the twelve-month period following August 23, 2020.
(6) Represents matching contributions to the Company's 401(k) savings plan.
(7) Bonus amounts under the annual incentive plan for the fiscal period ending December 31, 2020 have not been determined as at the date of this filing and are thus not calculable.
(8) Represents life insurance premiums.

Narrative Disclosure to Summary Compensation Table

The compensation program for the Company's named executive officers for 2020 had three components: base salary, annual cash bonus and equity grants.

Annual Base Salary

Other than Mr. Andreeff, we have entered into employment agreements with each of our named executive officers that establish annual base salaries, which are reviewed periodically by our Compensation Committee in order to compensate our named executive officers for the satisfactory performance of duties to the Company. Annual base salaries are intended to provide a fixed component of compensation to our named executive officers, reflecting their skill sets, experience, roles and responsibilities. Base salaries for our named executive officers have generally been set at levels deemed necessary to attract and retain individuals with superior talent. There were no adjustments made to the base salaries for the Company's named executive officers for the fiscal year 2020, as compared to fiscal year 2019.

Pursuant to the Interim President and CEO Employment Letter Agreement entered into with Mr. Andreeff on August 23, 2020, Mr. Andreeff has elected to take no additional compensation in return for his service as Interim President and Chief Executive Officer. Additionally, since he is not a member of any Board committees, Mr. Andreeff is not currently eligible for any cash retainer, which the Company only pays to the Chairs of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee.

Annual Cash Bonus

In 2020, each of the Company's named executive officers (other than Mr. Andreeff) had a target bonus, set forth as a percentage of annual base salary. The Board did not make any changes to the target bonuses of the named executive officers, as a percentage of base salary, for 2020. In 2020, target bonuses for Ms. LaViscount and Mr. Sackier were 40% of base salary. Mr. Deschamps' target bonus was set at 55% of base salary.

In March 2020, the Compensation Committee recommended, and the Board approved, performance targets for fiscal 2020 that it would consider in approving bonus payments for 2020. These targets included various corporate objectives related to company revenue goals, financing goals, regulatory submissions, and compliance goals.

Equity-Based Awards

Stock Options

Our equity-based incentive awards which are mainly comprised of stock options are designed to align our interests with those of our employees and consultants, including our named executive officers. Our Compensation

Committee has responsibility for granting equity-based incentive awards to our named executive officers. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. Our executives generally are awarded an initial new hire grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

In March 2019, our Compensation Committee recommended, and our Board approved, the grant of an option to purchase 4,571 shares of common stock to Mr. Deschamps, an option to purchase 2,857 shares of common stock to Ms. LaViscount and an option to purchase 2,857 shares of common stock to Dr. Sackier pursuant to the 2018 Plan. Each of these stock options has an exercise price equal to the fair market value of a share of common stock as of the grant date, as determined in accordance with our 2018 Plan, and vests in equal monthly installments over the 48-month period following the grant date.

In September 2019, our Compensation Committee recommended, and our Board approved, the grant of an option to purchase 4,285 shares of common stock to Ms. LaViscount pursuant to the 2018 Plan. The stock option has an exercise price equal to the fair market value of a share of common stock as of the grant date, as determined in accordance with our 2018 Omnibus Incentive Plan (as amended, the "2018 Plan"). 25% of the shares subject to the grant vest on September 23, 2020, and the remaining shares vest in equal monthly installments over the remaining 36 months.

In April 2020, our Compensation Committee approved, the grant of an option to purchase 1,428 shares of common stock to Mr. Sackier. The stock option has an exercise price equal to the fair market value of a share of common stock as of the grant date, as determined in accordance with our 2018 Plan, and vests in annual installments on each of the first four anniversaries of the date of grant subject to the holder's continuous service with the Company.

In October 2020, our Compensation Committee approved, the grant of an option to purchase 1,714 shares of common stock to Mr. Sackier, and an option to purchase 2,857 shares of common stock to Ms. LaViscount pursuant to the 2018 Plan. Each of these stock options has an exercise price equal to the fair market value of a share of common stock as of the grant date, as determined in accordance with our 2018 Plan, and vests in annual installments on each of the first two anniversaries of the date of grant subject to the holder's continuous service with the Company or earlier upon a Termination of Employment without Cause (as such terms are defined in the 2018 Plan).

Salary-for-Stock Program

In December 2019, we entered into an arrangement, as approved by our Board, with each of Mr. Deschamps and Ms. LaViscount whereby Mr. Deschamps and Ms. LaViscount elected to receive shares of common stock in lieu of a portion of each of their respective cash salary compensation. Mr. Deschamps and Ms. LaViscount elected to reduce their base cash salaries by approximately 19% and 17%, respectively, in exchange for fully vested shares of restricted stock granted pursuant to the 2018 Plan. The value of the shares is equal in value to the amount of cash salary forgone, with the actual number of shares issuable on each payroll date calculated based on the closing trading price of our common stock on the Nasdaq Capital Market as of such payroll date. Mr. Deschamps' and Ms. LaViscount's elections to receive restricted stock awards in lieu of cash salary compensation were effective beginning with the December 13, 2019 payroll date and remained in place until May 11, 2020 for Mr. Deschamps and August 11, 2020 for Ms. LaViscount. As of December 31, 2020, Mr. Deschamps had received 2,135 shares and Ms. LaViscount had received 2,413 shares pursuant to these elections.

Retirement Benefits and Other Compensation

Our named executive officers do not participate in, or otherwise receive any benefits under, any pension or deferred compensation plan sponsored by us. During 2019, we matched contributions made by our employees, including our named executive officers, to the Company's 401(k) savings plan. In 2020, we suspended the safe harbor match and moved to a discretionary, profit-sharing match and began providing life insurance benefits to our named executive officers. Our named executive officers were eligible to participate in our employee benefits, including health insurance benefits, on the same basis as our other employees. We generally do not provide perquisites or personal benefits except in limited circumstances.

Employment Agreements and Payments upon Termination or Change in Control

Philippe Deschamps

On June 13, 2014, we entered into an employment agreement with Philippe Deschamps to serve as our President and Chief Executive Officer. We amended the employment agreement on September 1, 2014. Pursuant to the employment agreement, Mr. Deschamps initially received a base salary at an annualized rate of $250,000, which was subsequently increased to $400,000 following the Company's achievement of certain financing thresholds. On April 17, 2017, the Board approved an increase of his base salary to $416,000. In addition to Mr. Deschamps' base salary, he had the opportunity to receive a target annual bonus of 30% of the base salary, conditional upon, and subject to upward or downward adjustment based upon, achievements and individual goals to be established in good faith by the Board of Directors and Mr. Deschamps. On April 26, 2018, the Compensation Committee recommended to the Board, and the Board approved a 3% increase to Mr. Deschamps' base salary to $428,480. On March 5, 2019, the Compensation Committee recommended to the Board and the Board approved, a 17% increase to Mr. Deschamps' base salary to $501,000 effective March 31, 2019 and a target annual bonus of 55% of such salary.

The employment agreement provided that if Mr. Deschamps was terminated without cause or if Mr. Deschamps resigned for good reason (each as defined in Mr. Deschamps' employment agreement), Mr. Deschamps would be entitled to an aggregate amount equal to the sum of his base salary and the earned portion of his annual bonus paid for the year preceding the year of his termination of which such amount is to be paid in equal monthly installments during the twelve month period following such termination of employment.

On August 23, 2020, the Company entered into a separation agreement with Philippe Deschamps. Pursuant to the separation agreement, Mr. Deschamps resigned from all positions as an officer or employee of the Company and all of the Company's subsidiaries and as a member of the Board effective as of such date. The separation agreement provided that Mr. Deschamps would receive certain benefits that he was entitled to receive under his employment agreement, as amended, in connection with a termination for good reason. Accordingly, under the separation agreement, subject to non-revocation of a general release and waiver of claims in favor of the Company, the Company agreed to pay Mr. Deschamps a total of $501,000 less required deductions and withholdings, in equal monthly installments during the twelve-month period following the date of the separation agreement. Mr. Deschamps remains subject to the non-compete and non-solicitation provisions in his employment agreement during the twelve-month period following the Mr. Deschamps' date of termination, and pursuant to the separation agreement, has agreed to certain customary standstill restrictions through the end of the period that is two years from the separation date.

Joyce LaViscount

On October 19, 2015, we entered into an employment agreement with Joyce LaViscount to serve as our Chief Financial Officer and Chief Operating Officer. Pursuant to the employment agreement, Ms. LaViscount received a base salary at an annualized rate of $300,000 for her employment term, which is at-will. On April 17, 2017, the Board approved an increase of her base salary to $336,000. In addition to Ms. LaViscount's base salary, she had the opportunity to receive a target annual bonus of 25% of the base salary, conditional upon, and subject to upward or downward adjustment based upon achievements and individual goals to be established in

good faith by our Chief Executive Officer and Ms. LaViscount. On April 26, 2018, the Compensation Committee recommended to the Board, and the Board approved, a 3% increase to Ms. LaViscount's base salary to $346,080. On March 5, 2019, the Compensation Committee recommended to the Board, and the Board approved, a 12% increase to Ms. LaViscount's base salary to $387,080, effective March 31, 2019, and a target annual bonus of 40% of such salary.

If Ms. LaViscount is terminated without cause or if she resigns for good reason (each as defined in Ms. LaViscount's employment agreement), Ms. LaViscount is entitled to an aggregate amount equal to the sum of her base salary and the earned portion of her annual bonus paid for the year preceding the year of her termination, of which such amount is to be paid in equal monthly installments during the twelve month period following such termination of employment.

Jonathan Sackier

On December 1, 2014, we entered into an employment agreement with Jonathan Sackier to serve as our Chief Medical Officer. Pursuant to the employment agreement, Dr. Sackier received a base salary at an annualized rate of $300,000 for his employment terms, which is at-will. In addition to Dr. Sackier's base salary, he shall have the opportunity to receive a target annual bonus of 25% of the base salary, conditional upon, and subject to upward or downward adjustment based upon, achievements and individual goals to be established in good faith by our Chief Executive Officer and Dr. Sackier. On April 17, 2017, our Board of Directors approved a 4% increase in Dr. Sackier's base salary to $312,000. On April 26, 2018, the Compensation Committee recommended to the Board, and the Board approved a 3% increase to Dr. Sackier's base salary to $324,480. On March 5, 2019, the Compensation Committee recommended to the Board and the Board approved, a 12% increase to Dr. Sackier's base salary to $360,000 effective March 31, 2019 and a target annual bonus of 40% of such salary. On December 1, 2019, Dr. Sackier agreed to take a temporary salary reduction to $200,000. This salary reduction remained in place throughout fiscal year 2020.

If Dr. Sackier is terminated without cause or if he resigns for good reason (each as defined in Dr. Sackier's employment agreement), Dr. Sackier is entitled to an aggregate amount equal to the sum of his base salary and the earned portion of his annual bonus paid for the year preceding the year of his termination, of which such amount is to be paid in equal monthly installments during the twelve month period following such termination of employment.

Dane C. Andreeff

On August 23, 2020, we entered into an Interim President and CEO Employment Letter Agreement with Mr. Andreeff. Mr. Andreeff has elected to take no additional compensation in return for his service as Interim President and Chief Executive Officer. However, Mr. Andreeff will continue to be eligible to receive the equity retainer granted annually to the Company's non-employee directors. Currently, pursuant to the non-employee director compensation policy that the Company adopted effective as of the date of the 2020 annual meeting of stockholders, the Company's non-employee directors receive an annual equity retainer equal to $20,000 delivered in the form of options to purchase shares of the Company's Class A Common Stock. Since he will not be a member of any Board committees, Mr. Andreeff is not eligible for any cash retainer, which the Company only pays to the Chairs of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee.

Equity Incentive Plans

Our named executive officers all have outstanding awards under (i) our 2014 Equity Incentive Plan (as amended, the "2014 Plan"), (ii) our 2016 Omnibus Incentive Plan (as amended, the "2016 Plan"), and (iii) the 2018 Plan.

Under the 2014 Plan, all awards vest immediately upon the Company's public announcement of a change of control. Under the 2014 Plan, a change of control is generally (i) the direct or indirect acquisition by any person or related group of persons of beneficial ownership of securities possessing more than 50% of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's shareholders; (ii) a change in the composition of the Board over a period of 36 months or less such that a majority of the Board members ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who are continuing directors; (iii) the sale or exchange by the Company (in one or a series of transactions) of all or substantially all of its assets to any other person or entity; or (iv) approval by the shareholders of the Company of a plan to dissolve and liquidate the Company. However, all awards held by named executive officers under the 2014 Plan were fully vested as of December 31, 2020.

Under the 2016 Plan and the 2018 Plan, the Compensation Committee may provide, in individual award agreements or in any other written agreement between a participant and us, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a termination of employment or change in control. Accordingly, in October 2020 when the compensation committee granted stock options to our named executive officers, the individual award agreements provided for accelerated vesting of such options upon termination of employment without "Cause" or for "Good Reason" (each as defined in the 2018 Plan) or upon a change in control.

Outstanding Equity Awards at December 31, 2020

The following table sets forth certain information about equity awards granted to our named executive officers that remain outstanding as of December 31, 2020.

Stock Options

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Dane C. Andreeff	428	143(1)	363.30	8/8/2027
	428	0(2)	384.65	5/15/2028
	511	0(3)	236.60	3/28/2029
	875	875(4)	19.08	6/10/2030
Philippe Deschamps (5)	0			
Joyce LaViscount	571	0(6)	438.20	3/16/2025
	4,285	0(7)	112.00	10/21/2025
	3,428	0(8)	187.25	7/13/2026
	3,428	1,143(9)	284.55	4/17/2027
	1,476	809(10)	384.65	5/15/2028
	714	2,143(11)	236.60	3/28/2029
	1,339	2,946(12)	60.55	9/23/2029
	0	2,857(13)	13.825	10/5/2030
Jonathan Sackier	2,285	0(14)	445.20	12/8/2024
	3,428	0(8)	187.25	7/13/2026
	3,428	1,143(9)	284.55	4/17/2027
	1,476	809(10)	384.65	5/15/2028
	714	2,143(11)	236.60	3/28/2029
	0	1,428(15)	11.20	4/16/20230
	0	1,714(13)	13.825	10/5/2030

(1) This option was granted on August 8, 2017. The shares vest in equal annual installments over 4 years from the date of grant.
(2) This option was granted on May 17, 2018. All of the shares subject to the option have vested.
(3) This option was granted on March 28, 2019. All of the shares subject to the option have vested.
(4) This option was granted on June 10, 2020. The shares vest in monthly annual installments over 12 months from the date of grant.
(5) Following the termination of Mr. Deschamps' employment on August 23, 2020, his remaining unvested options were forfeited pursuant to the terms of the applicable award agreements.
(6) This option was granted on March 16, 2015. All of the shares subject to the option have vested.
(7) This option was granted on October 21, 2015. All of the shares subject to the option have vested.
(8) This option was granted on July 13, 2016. All of the shares subject to the option have vested.
(9) This option was granted on April 17, 2017. The shares vest in equal monthly installments over 48 months from the date of grant.
(10) This option was granted on May 15, 2018. The shares vest in equal monthly installments over 48 months from the date of grant.
(11) This option was granted on March 28, 2019. The shares vest in equal annual installments over 4 years from the date of grant.
(12) This option was granted on September 23, 2019. 25% of the shares subject to the grant vest on September 23, 2020, and the remaining shares vest in equal monthly installments over the remaining 36 months.
(13) This option was granted on October 5, 2020. The shares vest in equal annual installments over 2 years from the date of grant.
(14) This option was granted on December 8, 2014. All of the shares subject to the option have vested.
(15) This option was granted on April 16, 2020. The shares vest in equal annual installments over 4 years from the date of grant.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Certain Related-Person Transactions

The following includes a summary of transactions since January 1, 2017 to which we have been a party, in which the amount involved in the transaction exceeded $120,000 (which is less than 1% of the average of our total assets at year end for the last two completed fiscal years), and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our voting securities or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest. Other than described below, there have not been, nor are there currently any proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which include equity and other compensation, termination, change in control and other arrangements, which are described under "Executive Compensation."

Consulting Agreement with Montel Media, Inc.

In April 2016, we entered into a consulting agreement with Montel Media, Inc. ("Montel Media"), an owner of over 5% of our Common Stock at the time, pursuant to which Montel Media provides consulting services for the promotion of our clinical trials and ongoing media and marketing strategies. Under the agreement, Montel Media receives $15,000 per month. This consulting agreement was terminated in February 2018. We paid Montel Media $0, $45,000 and $0.2 million for the years ended December 31, 2019, 2018 and 2017, respectively, pursuant to the consulting agreement.

Consulting Agreement with Clinvue LLC

Our Chief Medical Officer, Jonathan Sackier, was a founding member of Clinvue LLC, which provided regulatory advisory services for the Company. Clinvue ceased operations as of December 31, 2018. We paid Clinvue LLC approximately $0.1 million for consulting services in each of the years ended December 31, 2018 and 2017. We made no payments to Clinvue for the year ended December 31, 2019.

November 2019 Public Offering

In November 2019, we issued 137,571 shares of our common stock in an underwritten public offering. Entities affiliated with Maple Leaf Partners, LP, for which Dane C. Andreeff, our Interim President and Chief Executive Officer and director, serves as General Partner and Portfolio Manager, purchased approximately $0.2 million, or 16,326, of the shares of common stock offered thereby. Each share of common stock was purchased at a price of $12.25 per share.

October 2020 Private Placement

In October 2020, we issued 187,646 shares of common stock and warrants to purchase an aggregate of 93,817 shares of common stock, for an aggregate purchase price of approximately $3.4 million. Entities affiliated with Maple Leaf Partners, L.P., for which Dane C. Andreeff, our Interim President and Chief Executive Officer serves as General Partner and Portfolio Manager, purchased 33,778 shares and warrants to purchase 16,887 shares for an aggregate purchase price of $620,000, and Ms. LaViscount, our Chief Financial Officer and Chief Operating Officer purchased 1,089 shares and warrants to purchase 544 shares for an aggregate purchase price of $20,000. Such affiliated purchasers participated on the same terms and conditions as all other purchasers, except that they had a purchase price of $18.354 per unit, and their warrants have an exercise price of $16.1665 per share.

Pursuant to the securities purchase agreement for the October 2020 Private Placement, if we issue any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination

thereof, with certain exceptions, within twelve months of the closing of the private placement, each purchaser who subscribed for at least $250,000 in the private placement has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

Indemnification

The Company provides indemnification for its directors and officers so that they will be free from undue concern about personal liability in connection with their service to the Company. Under the Company's Amended and Restated Bylaws, the Company is required to indemnify its directors and officers to the extent not prohibited under Delaware or other applicable law. The Company has also entered into indemnity agreements with certain officers and directors. These agreements provide, among other things, that the Company will indemnify the officer or director, under the circumstances and to the extent provided for in the agreement, for expenses, damages, judgments, fines and settlements he or she may be required to pay in actions or proceedings which he or she is or may be made a party by reason of his or her position as a director, officer or other agent of the Company, and otherwise to the fullest extent permitted under applicable law and the Company's Amended and Restated Bylaws.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the ownership of the Company's common stock as of January 11, 2021 by: (i) each director; (ii) each of our named executive officers; (iii) all executive officers and directors of the Company as a group; and (iv) all those known by the Company to be beneficial owners of more than five percent of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that we include shares of Common Stock issuable pursuant to the vesting of warrants and the exercise of stock options that are either immediately exercisable or exercisable within 60 days of January 11, 2021. These shares are deemed to be outstanding and beneficially owned by the person holding those warrants or options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. This table is based on information supplied by officers, directors and principal stockholders and Schedule 13D, Schedule 13G and Section 16 filings, if any, with the SEC. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o Helius Medical Technology, Inc., 642 Newtown Yardley Road, Suite 100, Newtown, Pennsylvania 18940.

	Beneficial Ownership (1)	
Beneficial Owner	Number of Shares of Common Stock	Percent of Total
Columbus Capital Management LLC (2)	160,805	9.9
A&B (HK) Company Limited (3)	71,306	4.6
Sabby Volatility Warrant Master Fund, Ltd. (4)	81,632	5.2
Philippe Deschamps (5)	22,371	1.4
Joyce LaViscount (6)	20,356	1.3
Jonathan Sackier (7)	31,522	2.0
Edward M. Straw (8)	3,773	*
Mitchell E. Tyler (9)	26,154	1.7
Blane Walter (10)	5,980	*
Dane C. Andreeff (11)	94,316	6.0
Jeffrey S. Mathiesen (12)	1,312	*
All current executive officers and directors as a group (7 persons) (13)	183,412	11.7

* Less than one percent.

(1) This table is based upon information supplied by officers, directors and principal stockholders. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 1,566,163 shares outstanding on January 11, 2021, adjusted as required by rules promulgated by the SEC.

(2) Includes 146,520 shares of Common stock, and 14,285 shares of Common stock issuable upon the exercise of warrants. Columbus Capital Management, LLC, which serves as the general partner and investment manager to each of Columbus Capital QP Partners, L.P., Columbus Capital Partners, L.P., and Columbus Capital Offshore QP Fund, LTD. (collectively "the Funds"), and Mr. Matthew D. Ockner, as Managing Member of Columbus Capital Management, LLC, with the power to exercise investment and voting discretion, may be deemed to be the beneficial owner of all shares of Common stock held by the

Funds. The business address of Matthew D. Ockner is 1 Embarcadero Center, Suite 1130, San Francisco, CA 94111. The percentage in this table reflects that the reporting persons may not exercise the warrants to the extent such exercise would cause the reporting persons to beneficially own a number of shares of common stock that would exceed 9.99% of our then outstanding common stock following such exercise.

(3) Includes 71,306 shares of Common stock. Dr. Lam Kong is the sole officer and director of each A&B and A&B Brother Limited ("A&B BVI"). The business address of A&B BVI is Trident Chambers, P.O. Box 146, Road Town, Tortola, British Virgin Islands. The business address of Dr. Lam Kong is Unit 2106, 21/F, Island Place Tower, 510 King's Road, North Point, Hong Kong.

(4) Includes 81,632 shares issuable upon the exercise of warrants. Sabby Volatility Warrant Master Fund, Ltd. ("Sabby"), Sabby Management, LLC ("Sabby Management") and Hal Mintz have shared voting and investment power with respect to these shares. Sabby Management serves as the investment manager of Sabby; Mr. Mintz is manager of Sabby Management. The address for Sabby is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. The address for Sabby Management and Mr. Mintz is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

(5) Mr. Deschamps stepped down from his roles as President and Chief Executive Officer and director effective August 23, 2020 upon mutual agreement with the Board. The information presented is based on the former officer's last filed Form 4 and company records.

(6) Includes 4,239 shares of Common stock, 15,573 shares of Common stock issuable upon the exercise of stock options, and 544 shares of Common stock issuable upon the exercise of warrants.

(7) Includes 20,096 shares of Common stock and 11,426 shares of Common stock issuable upon the exercise of stock options.

(8) Includes 71 shares of Common stock and 3,702 shares of Common stock issuable upon the exercise of stock options.

(9) Includes 23,701 shares of Common stock and 2,453 shares of Common stock issuable upon the exercise of stock options.

(10) Includes 2,414 shares of Common stock and 3,566 shares of Common stock issuable upon the exercise of stock options.

(11) Includes 40,586 shares of common stock and 9,116 shares of common stock issuable upon the exercise of warrants held by Maple Leaf Partners, L.P., 8,598 shares of common stock and 1,926 shares of common stock issuable upon the exercise of warrants held by Maple Leaf Partners I, L.P., 23,309 shares of common stock and 5,312 shares of common stock issuable upon the exercise of warrants held by Maple Leaf Discovery I, L.P., 1,684 shares of common stock and 533 shares of common stock issuable upon the exercise of warrants held by Maple Leaf Offshore, Ltd., 571 shares on common stock held directly by Mr. Andreeff and 2,679 shares of common stock issuable upon the exercise of stock options held directly by Mr. Andreeff. Mr. Andreeff has sole voting and dispositive power over shares held by Maple Leaf Partners, L.P., Maple Leaf Partners I, L.P., Maple Leaf Discovery I, L.P. and Maple Leaf Offshore, Ltd.

(12) Consists of 1,312 shares of Common Stock issuable upon the exercise of stock options.

(13) Includes 147,640 shares of Common Stock, 40,710 shares of Common stock issuable upon the exercise of stock options, and 17,433 shares of Common stock issuable upon the exercise of warrants.

DESCRIPTION OF SECURITIES

Description of Units

We are offering 647,772 Units, with each Unit consisting of one share of common stock and a Warrant to purchase 0.5 shares of our common stock (together with the shares of common stock underlying such Warrants) at a public offering price of $14.82 per Unit. Each Warrant included in the Units entitles its holder to purchase 0.5 shares of common stock at an exercise price of $16.302.

The securities of which the Units are composed (the "underlying securities") are being sold in this offering only as part of the units. However, the Units will not be certificated and the underlying securities comprising such Units are immediately separable. Each underlying security purchased in this offering will be issued independent of each other underlying security and not as part of a unit. Upon issuance, each underlying security may be transferred independent of any other underlying security, subject to applicable law and transfer restrictions.

Description of Warrants Included in the Units

The material terms and provisions of the Warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the Warrants is not complete, and is qualified in its entirety by, the provisions of the Warrant. For the complete terms of the Warrants, you should refer to the form of warrant filed as an exhibit to the registration statement of which this prospectus is a part.

Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company LLC, as warrant agent, the Warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Exercisability. The Warrants are immediately exercisable and will expire on the date that is five years after their original issuance. The Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice. In no event may the Warrants be net cash settled.

Exercise Limitation. A holder will not have the right to exercise any portion of the Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, such holder may increase its ownership, provided that in no event will the ownership exceed 9.99%, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Exercise Price. The Warrants will have an exercise price of $16.302 per share (110% of the per Unit offering price). The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise. If, at the time a holder exercises its Warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the Warrant to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Warrant.

Transferability. Subject to applicable laws, the Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. There is no established trading market for the Warrants being offered and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Warrants will be limited.

Fundamental Transactions. If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Warrants with the same effect as if such successor entity had been named in the warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the warrant following such fundamental transaction. Additionally, as more fully described in the Warrant, in the event of certain fundamental transactions, the holders of the Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the Warrants on the date of consummation of the transaction.

Rights as a Stockholder. Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Warrant.

Description of the Underwriter Warrants

The material terms and provisions of the underwriter warrants being offered pursuant to this prospectus are summarized above in the section entitled "Description of Warrants Included in the Units." The terms of the underwriter warrants are substantially similar to the terms of the warrants to be issued to investors, except that the exercise price of the underwriter warrants is 125% of the per Unit offering price and the expiration date is five years from the consummation of sales in this offering. The summary of some provisions of the underwriter warrants is not complete, and is qualified in its entirety by, the provisions of the underwriter warrant. For the complete terms of the underwriter warrants, you should refer to the form of underwriter warrant filed as an exhibit to the registration statement of which this prospectus is a part.

Description of Capital Stock

The following description of our capital stock and provisions of our Certificate of Incorporation and Amended and Restated Bylaws are summaries. You should also refer to the Certificate of Incorporation and the Amended and Restated Bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part.

General

Our Certificate of Incorporation authorizes us to issue up to 150,000,000 shares of common stock and 10,000,000 shares of preferred stock, par value $0.001 per share, all of which shares of preferred stock are currently undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

As of January 11, 2021, there were (i) 1,566,163 shares of common stock outstanding; (ii) no outstanding shares of preferred stock; (iii) 111,074 shares of common stock issuable upon the exercise of outstanding stock options; and (iv) 260,272 shares of common stock issuable upon the exercise of outstanding warrants. At a special meeting of our stockholders on December 28, 2020, our stockholders approved a reverse split of our outstanding common stock at a ratio in the range of 1-for-5 to 1-for-35 to be determined at the discretion of our Board of Directors, whereby each outstanding 5 to 35 shares would be combined, converted and changed into 1 share of our common stock, to enable the Company to comply with Nasdaq's continued listing requirements. Following such meeting, our board of directors approved a final reverse stock split ratio of 1-for-35. We filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation to effect the reverse stock split. The reverse stock split was effective as of 5:00 pm Eastern Time on December 31, 2020, and our common stock began trading on a split adjusted basis on The Nasadaq Capital Market and TSX on January 4, 2021. All share and per share amounts presented herein have been retroactively adjusted to reflect the reverse stock split.

Common Stock

Voting

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

Our board of directors has the authority under our Certificate of Incorporation, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Amended and Restated Bylaws

Our Certificate of Incorporation provides that the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board of directors, only be filled by a majority vote of the directors then serving on the board of directors, even though less than a quorum.

Our Amended and Restated Bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminate the right of stockholders to act by written consent without a meeting. Our Amended and Restated Bylaws also provide that only our Chairman of the board of directors, Chief Executive Officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our Amended and Restated Bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specify requirements as to the form and content of a stockholder's notice. At any meeting of stockholders for the election of directors at which a quorum is present, the election will be determined by a plurality of the votes cast by the stockholders entitled to vote at the election.

Our Certificate of Incorporation and Amended and Restated Bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 2/3% or more of our outstanding Common stock. As described above, our Certificate of Incorporation gives our board of directors the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Certificate of Incorporation or our Amended and Restated Bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable in such action. Our Certificate of Incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

Participation Rights of Investors in October 2020 Private Placement

Pursuant to the securities purchase agreement for the October 2020 Private Placement, if we issue any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the private placement, each purchaser who subscribed for at least $250,000 in the private placement has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

Registration Rights of A&B

Pursuant to the terms of convertible notes issued to A&B (HK) Company Limited in October 2015 and December 2015, we agreed to register any shares issued upon the conversion of such convertible notes upon the

request of A&B (HK) Company Limited. As of January 11, 2021, A&B (HK) Company Limited beneficially owned 71,306 shares of Common stock that were issued upon the conversion of such convertible notes.

Transfer Agent and Registrar

The transfer agent and the registrar for the Company is American Stock Transfer & Trust Company LLC, 6201 15th Avenue, Brooklyn, New York 11219; Telephone: 800-937-5449.

Common Stock Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “HSDT” and on the TSX under the symbol “HSM.” See “Prospectus Summary—Recent Developments” in this prospectus for important information about the listing of our common stock on The Nasdaq Capital Market.

UNDERWRITING

We are offering the Units described in this prospectus through the underwriter named below. Ladenburg Thalmann & Co. Inc. is acting as the representative of the underwriters in this offering. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase the number of our securities set forth opposite its name below.

Underwriter	Units
Ladenburg Thalmann & Co. Inc.	647,772
Total	647,772

A copy of the underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriter that it proposes to offer the Units directly to the public at the public offering price set forth on the cover page of this prospectus. Any securities sold by the underwriter to securities dealers will be sold at the public offering price less a selling concession not in excess of $0.71088 per share and $0.00048 per Warrant.

The underwriting agreement provides that the underwriter's obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriter that would permit a public offering of the Units, or the shares of common stock and Warrants included in the Units in any jurisdiction outside the United States where action for that purpose is required, including Canada. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal. No sales of our securities under this prospectus will be made to a resident of Canada.

The underwriter has advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriter by us.

	Per Unit(1)	Total	Total with Full Exercise of Overallotment
Public offering price	$ 14.82	$ 9,599,981.04	$ 11,039,951.52
Underwriting discount to be paid to the underwriter by us (8.0%)(2)(3)	$ 1.19	$ 770,978.23	$ 886,662.82
Proceeds to us (before expenses)	$ 13.634	$ 8,829,002.81	$ 10,153,328.70

(1) The public offering price and underwriting discount corresponds, in respect of the Units (i) a public offering price per share of common stock of $14.81 ($13.6252 net of the underwriting discount) and (ii) a public offering price per Warrant of $0.01 ($0.0092 net of the underwriting discount).
(2) We have also agreed to reimburse the accountable expenses of the underwriter, including legal fees, in this offering, up to a maximum of $92,000.
(3) We have granted a 45 day option to the underwriter to purchase up to an additional 97,164 shares of common stock and/or 48,582 Warrants at the public offering price per share of common stock and the public

offering price per Warrant set forth above less the underwriting discounts and commissions solely to cover over-allotments, if any.

We estimate the total expenses payable by us for this offering to be approximately $1.1 million, which amount includes (i) the underwriting discount of $0.8 million and (ii) reimbursement of the accountable expenses of the underwriter, including the legal fees of the underwriter and (iii) other estimated company expenses of approximately $350,000 which includes legal accounting printing costs and various fees associated with the registration and listing of the shares.

The securities we are offering are being offered by the underwriter subject to certain conditions specified in the underwriting agreement.

Underwriter's Warrants

As additional compensation to the underwriter upon consummation of this offering, we will issue to the underwriter or its designees warrants to purchase an aggregate number of shares of our common stock equal to 4.0% of the number of shares of common stock issued in this offering, at an exercise price per share equal to 125% of the public offering price (the "Underwriter's Warrants"). The Underwriter's Warrants will have a term of five years from the commencement of sales in this offering in accordance with FINRA Rule 5110(g)(8)(A).

Over-allotment Option

We have granted to the underwriter an option exercisable not later than 45 days after the date of this prospectus to purchase up to a number of additional shares of common stock and/or warrants equal to 15% of the number of shares of common stock sold in the primary offering and/or 15% of the warrants sold in the primary offering at the public offering price per share of common stock and the public offering price per Warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover overallotments, if any, made in connection with this offering. If any additional shares of common stock and/or Warrants are purchased, the underwriters will offer these shares of common stock and/or Warrants on the same terms as those on which the other securities are being offered.

Determination of Offering Price

Our common stock is listed on the Nasdaq Capital Market under the symbol "HSDT" and on the TSX under the symbol "HSM." See "Prospectus Summary—Recent Developments" for important information about the listing of our common stock on The Nasdaq Capital Market. We do not intend to apply for listing of the Warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriter. Among the factors considered in determining the public offering price of the Units were;

- the price of our common stock on The Nasdaq Capital Market during recent periods;
- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering, including discussions between the underwriters and prospective investors.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the securities sold in this offering. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the securities sold in this offering can be resold at or above the public offering price.

Lock-up Agreements

Our officers, directors and each of their respective affiliates and associated partners have agreed with the underwriter to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The underwriter may, in their sole discretion and without notice, waive the terms of any of these lock-up agreements.

Right of First Refusal

Upon completion of this offering, in certain circumstances, we have granted the representative a right of first refusal to act as lead bookrunner or placement agent in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends for nine months from the closing date of this offering. The terms of any such engagement of the representative will be determined by separate agreement.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company LLC.

Stabilization, Short Positions and Penalty Bids

The underwriter may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.
- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to the effect

that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we, nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including certain liabilities arising under the Securities Act or to contribute to payments that the underwriter may be required to make for these liabilities.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of material U.S. federal income considerations relating to the purchase, ownership and disposition of our common stock or Warrants. This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated or proposed thereunder and current administrative and judicial interpretations thereof, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. We have not sought and will not seek any rulings from the Internal Revenue Service, or the IRS, regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position.

This discussion is limited to U.S. holders and non-U.S. holders who hold our common stock or Warrants as capital assets within the meaning of Section 1221 of the Code (generally, as property held for investment). This discussion does not address all aspects of U.S. federal income taxation, such as the U.S. alternative minimum income tax and the additional tax on net investment income, nor does it address any aspect of state, local or non-U.S. taxes, or U.S. federal taxes other than income taxes, such as federal estate taxes. This discussion does not consider any specific facts or circumstances that may apply to a holder and does not address the special tax considerations that may be applicable to particular holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- persons required for U.S. federal income tax purposes to conform the timing of income accruals to their financial statements under Section 451(b) of the Code;
- controlled foreign corporations;
- passive foreign investment companies;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- certain U.S. expatriates;
- U.S. persons that have a “functional currency” other than the U.S. dollar;
- persons that acquire our common stock or Warrants as compensation for services;
- owners that hold our common stock or Warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their places of organization or formation) and their investors; and
- partnerships or other entities treated as partnerships for U.S. federal income tax purposes and their investors.

If any entity taxable as a partnership for U.S. federal income tax purposes holds our common stock or Warrants, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. An investor in a partnership or entity treated as disregarded for U.S. federal income tax purposes should consult his, her or its own tax advisor regarding the applicable tax consequences relating to the purchase, ownership and disposition of our common stock or Warrants.

For purposes of this discussion, the term "U.S. holder" means a beneficial owner of our common stock or Warrants that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (i) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (ii) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

A "non-U.S. holder" is a beneficial owner of our common stock or Warrants that is, for U.S. federal income tax purposes, an individual, corporation, estate or trust that is not a U.S. holder.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of purchasing, holding and disposing of our common stock or Warrants.

U.S. Holders

Purchase of Units

For U.S. federal income tax purposes, the purchase of a Unit will be treated as the purchase of two components: a component consisting of one share of our common stock and a component consisting of one warrant to purchase 0.5 shares of our common stock. The purchase price for each Unit will be allocated between its components in proportion to the relative fair market value of each at the time the Unit is purchased by the holder. This allocation of the purchase price for each Unit will establish a holder's initial tax basis for U.S. federal income tax purposes in the shares and warrants that compose each Unit.

Exercise of Warrants

A U.S. holder generally will not recognize gain or loss on the exercise of a warrant and related receipt of shares of our common stock (unless cash is received in lieu of the issuance of a fractional share of our common stock). A U.S. holder's initial tax basis in the shares of our common stock received upon the exercise of a warrant will be equal to the sum of (a) such U.S. holder's tax basis in such warrant plus (b) the exercise price paid by such U.S. holder on the exercise of such warrant. A U.S. holder's holding period for the shares of our common stock received upon the exercise of a warrant will begin on the day after the date that the warrant is exercised.

In certain limited circumstances, a U.S. holder may be permitted to undertake a cashless exercise of warrants into shares of our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into shares of common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant described in the preceding paragraph. U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

Certain Adjustments to the Warrants

An adjustment to the number of shares of our common stock that will be issued upon the exercise of a warrant, or an adjustment to the exercise price of a warrant, may be treated as a constructive distribution to a U.S. holder of the warrant or share depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of

preventing dilution of the interest of the holders thereof generally should not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See the more detailed discussion of the rules applicable to distributions made by us under the heading "Distributions on Common Stock" below.

Expiration of the Warrants without Exercise

Upon the lapse or expiration of a warrant, a U.S. holder will recognize a loss in an amount equal to such U.S. holder's tax basis in the warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the warrant is held for more than one year. Deductions for capital losses are subject to certain limitations.

Distributions on Common Stock

If we pay distributions of cash or property with respect to our common stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants"), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder's investment, up to such holder's tax basis in its shares of our common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition."

Gain on Sale, Exchange or Other Taxable Disposition

Upon the sale or other taxable disposition of common shares or Warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in such common shares or Warrants sold or otherwise disposed of. Such gain or loss generally will be long-term capital gain or loss if, at the time of the sale or other disposition, the common shares or Warrants have been held by the U.S. holder for more than one year. Preferential tax rates may apply to long-term capital gain of a U.S. holder that is an individual, estate, or trust. Deductions for capital losses are subject to certain limitations.

Non-U.S. Holders

Distributions on Common Stock

If we pay distributions of cash or property with respect to our common stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants"), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in its shares of our common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition." Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. In the case of any constructive distribution, it is possible that this tax would be withheld from any amount owed to the non-U.S. holder, including, but not limited to, distributions of cash, common stock or sales proceeds subsequently paid or credited to that holder. If we are unable to determine, at the time of payment of a distribution, whether the distribution will constitute a dividend, we may nonetheless choose to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations.

Distributions that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States are generally not subject to the 30% withholding tax if the non-U.S. holder

provides a properly executed IRS Form W-8ECI stating that the distributions are not subject to withholding because they are effectively connected with the non-U.S. holder's conduct of a trade or business in the United States. If a non-U.S. holder is engaged in a trade or business in the United States and the distribution is effectively connected with the conduct of that trade or business, the distribution will generally have the consequences described above for a U.S. holder (subject to any modification provided under an applicable income tax treaty). Any U.S. effectively connected income received by a non-U.S. holder that is treated as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty).

A non-U.S. holder who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E, as applicable, and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty generally may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Gain on Sale, Exchange or Other Taxable Disposition

Subject to the discussion below in "—Information Reporting and Backup Withholding" and "—Foreign Account Tax Compliance Act," a non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a sale, exchange or other taxable disposition of our common stock or Warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to a U.S. holder, and, if the non-U.S. holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the amount by which such non-U.S. holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition; or
- we are or were a "U.S. real property holding corporation" during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" (within the meaning of the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business.

Information Reporting and Backup Withholding

Distributions on, and the payment of the proceeds of a disposition of, our common stock or Warrants generally will be subject to information reporting if made within the United States or through certain U.S.-related financial intermediaries. Information returns are required to be filed with the IRS and copies of information returns may be made available to the tax authorities of the country in which a holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding may also apply if the holder fails to provide certification of exempt status or a correct U.S. taxpayer identification number and otherwise comply with the applicable backup withholding requirements.

Generally, a holder will not be subject to backup withholding if it provides a properly completed and executed IRS Form W-9 or appropriate IRS Form W-8, as applicable. Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be refunded or credited against the holder's U.S. federal income tax liability, if any, provided certain information is timely filed with the IRS.

Foreign Account Tax Compliance Act

Legislation commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on dividends paid to certain non-U.S. entities (including certain intermediaries) unless such persons comply with FATCA's information reporting and withholding regime. We will not pay any additional amounts to stockholders in respect of any amounts withheld. This regime and its requirements are different from, and in addition to, the certification requirements described elsewhere in this discussion. If a payment is both subject to withholding under FATCA and subject to withholding tax discussed above, the withholding under FATCA may be credited against, and therefore reduce, such other withholding tax.

The United States has entered into, and continues to negotiate, intergovernmental agreements, or IGAs, with a number of other jurisdictions to facilitate the implementation of FATCA. An IGA may significantly alter the application of FATCA and its information reporting and withholding requirements with respect to any particular investor. FATCA is particularly complex and its application remains uncertain. Prospective investors should consult their own tax advisors regarding how these rules may apply in their particular circumstances.

LEGAL MATTERS

Honigman LLP, Kalamazoo, Michigan, will issue a legal opinion as to the validity of the securities offered by this prospectus. Ellenoff Grossman & Schole LLP, New York, New York is acting as counsel for the underwriter in connection with certain legal matters in connection with this offering.

EXPERTS

The consolidated financial statements as of December 31, 2019 and 2018 and for the years then ended included in this Prospectus and in the Registration Statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting, appearing elsewhere herein. The report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Helius Medical Technologies, Inc.
Newtown, Pennsylvania

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Helius Medical Technologies, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred substantial net losses since its inception, has an accumulated deficit of $104.8 million as of December 31, 2019 and the Company expects to incur further net losses in the development of its business. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2017.

Philadelphia, Pennsylvania
March 12, 2020, except for the "2020 Reverse Stock Split" paragraph of Note 1, as to which the date is January 19, 2021.

Helius Medical Technologies, Inc.
Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	As of December 31, 2019	As of December 31, 2018
ASSETS		
Current assets		
Cash	$ 5,459	$ 25,583
Accounts receivable, net	210	177
Other receivables	364	98
Inventory, net of reserve	598	392
Prepaid expenses	610	447
Other current assets	—	264
Total current assets	7,241	26,961
Property and equipment, net	712	554
Other assets		
Goodwill	1,242	—
Intangible assets, net	582	—
Operating lease right-of-use asset, net	552	—
Non-current receivables	—	294
Other assets	18	18
Total other assets	2,394	312
TOTAL ASSETS	**$ 10,347**	**$ 27,827**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,676	$ 2,392
Accrued liabilities	1,519	1,812
Operating lease liability	172	—
Derivative financial instruments	5	13,769
Deferred revenue	430	—
Total current liabilities	3,802	17,973
Non-current liabilities		
Operating lease liability	465	—
Deferred revenue	245	—
TOTAL LIABILITIES	**4,512**	**17,973**
Commitments and contingencies (Note 7)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2019 and December 31, 2018	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 877,672 and 737,938 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	1	1
Additional paid-in capital	111,509	105,436
Accumulated other comprehensive loss	(902)	(591)
Accumulated deficit	(104,773)	(94,992)
TOTAL STOCKHOLDERS' EQUITY	**5,835**	**9,854**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 10,347**	**$ 27,827**

(The accompanying notes are an integral part of these consolidated financial statements.)

Helius Medical Technologies, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands except shares and per share data)

	Year Ended December 31,	
	2019	2018
Revenue:		
Product sales, net	$ 1,454	$ —
Fee revenue	37	—
License revenue	5	478
Total operating revenue	**1,496**	**478**
Cost of sales:		
Cost of product sales	846	—
Gross profit	**650**	**478**
Operating expenses:		
Research and development	8,061	9,939
Selling, general and administrative	16,521	17,214
Amortization expense	64	—
Total operating expenses	**24,646**	**27,153**
Operating loss	**(23,996)**	**(26,675)**
Other income (expense):		
Other income	95	63
Change in fair value of derivative financial instruments	14,113	(3,577)
Foreign exchange gain	7	1,566
Total other income (expense)	**14,215**	**(1,948)**
Net loss	**(9,781)**	**(28,623)**
Other comprehensive loss:		
Foreign currency translation adjustments	(311)	(638)
Comprehensive loss	**$ (10,092)**	**$ (29,261)**
Net loss per share		
Basic	**$ (12.99)**	**$ (43.97)**
Diluted	**$ (12.99)**	**$ (43.97)**
Weighted average shares outstanding		
Basic	**752,932**	**651,034**
Diluted	**752,932**	**651,034**

(The accompanying notes are an integral part of these consolidated financial statements.)

Helius Medical Technologies, Inc.
Consolidated Statements of Stockholders' Equity
(Except shares data, amounts in thousands)

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2017	**—**	**$ —**	**576,520**	**$ 52,230**	**$ 6,602**	**$ (66,369)**	**$ 47**	**$ (7,490)**
Proceeds from the issuance of common stock and accompanying warrants from April 2018 Offering	—	—	70,376	18,400	—	—	—	18,400
Fair value of liability-classified warrants issued in connection with April 2018 Offering	—	—	—	(7,372)	—	—	—	(7,372)
Share issuance costs – April 2018 Offering	—	—	—	(1,273)	—	—	—	(1,273)
Proceeds from the exercise of stock options and warrants	—	—	21,033	4,637	—	—	—	4,637
Stock-based compensation expense – prior to change in corporate domicile	—	—	—	—	1,047	—	—	1,047
Reclassification of liability-classified warrants upon exercise	—	—	—	3,748	—	—	—	3,748
Settlement of vested restricted stock units, net of taxes	—	—	20	—	(2)	—	—	(2)
Reclassification of exercised compensation options and warrants from additional paid-in capital	—	—	—	110	(110)	—	—	—
Reclassification of April 2016 compensation options and warrants from additional paid-in capital to derivative financial instruments due to change in functional currency	—	—	—	—	(1,586)	—	—	(1,586)
Reclassification of USD denominated warrants from derivative financial instruments to additional paid-in capital due to change in functional currency	—	—	—	—	2,478	—	—	2,478
Reclassification of equity-classified stock options to stock-based compensation liability due to change in functional currency	—	—	—	—	(4,182)	—	—	(4,182)
Reclassification from other current liabilities due to exercise of stock options	—	—	—	32	—	—	—	32
Reclassification of non-employee options recorded as derivative financial instruments due to modification of options	—	—	—	—	1,206	—	—	1,206
Reclassification of stock-based compensation due to modification of options	—	—	—	—	10,338	—	—	10,338
Reclassification upon change in corporate domicile	667,949	1	(667,949)	(70,512)	70,511	—	—	—
Proceeds from issuance of common stock in connection with November 2018 Offering	69,696	—	—	—	20,126	—	—	20,126
Proceeds from exercise of stock options	293	—	—	—	26	—	—	26
Share issuance costs – November 2018 Offering	—	—	—	—	(1,867)	—	—	(1,867)
Stock-based compensation expense – after change in corporate domicile	—	—	—	—	849	—	—	849
Net loss	—	—	—	—	—	(28,623)	—	(28,623)
Foreign currency translation adjustments	—	—	—	—	—	—	(638)	(638)

	Common Stock, $0.001 par value		Common Stock, no par value		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2018	**737,938**	**$ 1**	**—**	**$ —**	**$ 105,436**	**$ (94,992)**	**$ (591)**	**$ 9,854**
Proceeds from the issuance of common stock from November 2019 Offering	137,571	—	—	—	1,685	—	—	1,685
Share issuance costs – November 2019 Offering	—	—	—	—	(553)	—	—	(553)
Proceeds from exercise of stock options and warrants	2,136	—	—	—	215	—	—	215
Settlement of vested restricted stock units, net of taxes	27	—	—	—	—	—	—	—
Reclassification of derivative financial instruments from exercise of warrants	—	—	—	—	35	—	—	35
Stock-based compensation	—	—	—	—	4,691	—	—	4,691
Foreign currency translation adjustments	—	—	—	—	—	—	(311)	(311)
Net loss	—	—	—	—	—	(9,781)	—	(9,781)
Balance as of December 31, 2019	**877,672**	**$ 1**	**—**	**$ —**	**$ 111,509**	**$ (104,773)**	**$ (902)**	**$ 5,835**

(The accompanying notes are an integral part of these consolidated financial statements.)

Helius Medical Technologies, Inc.
Consolidated Statements of Cash Flows
(Amounts in thousands)

	Year Ended December 31, 2019	2018
Cash flows from operating activities		
Net loss	$ (9,781)	$ (28,623)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	127	59
Amortization expense	64	—
Provision for doubtful accounts	220	—
Change in fair value of derivative financial instruments	(14,113)	3,577
Stock-based compensation expense	4,691	8,095
Unrealized foreign exchange loss (gain)	70	(1,711)
Changes in operating assets and liabilities:		
Accounts receivable	(438)	(259)
Other receivables	(278)	394
Prepaid expenses	(163)	(95)
Inventory	(206)	(392)
Other current assets	264	(264)
Operating lease liability	(13)	—
Account payable	(1,116)	(1,087)
Accrued liabilities	(327)	685
Net cash used in operating activities	**(20,999)**	**(19,621)**
Cash flows from investing activities		
Purchase of property and equipment	(278)	(440)
Business acquisitions, net of cash acquired	(416)	—
Internally developed software	(75)	—
Net cash used in investing activities	**(769)**	**(440)**
Cash flows from financing activities		
Proceeds from the issuances of common stock and warrants	1,685	38,526
Share issuance costs	(247)	(3,161)
Proceeds from the exercise of stock options and warrants	215	4,663
Net cash provided by financing activities	**1,653**	**40,028**
Effect of foreign exchange rate changes on cash	(9)	54
Net (decrease) increase in cash	(20,124)	20,021
Cash at beginning of year	25,583	5,562
Cash at end of year	**$ 5,459**	**$ 25,583**
Supplemental disclosure of non-cash cash activities		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	—	—
Supplemental schedule of non-cash investing and financing activities		
Share issuance costs included in accounts payable and accrued liabilities	$ 358	$ 52
Reclassification of derivative instruments from warrant exercise	35	—
Noncash items related to Heuro acquisition	1,227	—

(The accompanying notes are an integral part of these consolidated financial statements.)

Helius Medical Technologies, Inc.
Notes to the Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS

Helius Medical Technologies, Inc. (the "Company"), is neurotech company focused on neurological wellness. The Company's purpose is to develop, license and acquire unique and non-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

The Company's first product, known as the Portable Neuromodulation Stimulator ("PoNS™"), is an active, therapeutic, class II medical device authorized for sale in Canada intended as a short term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with therapeutic activities ("PoNS Treatment™"). It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"), and it is currently under review for clearance by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

On December 21, 2018, the Company's wholly owned subsidiary, NeuroHabilitation Corporation, changed its name to Helius Medical, Inc ("HMI"). On January 31, 2019, the Company formed another wholly owned subsidiary, Helius NeuroRehab, Inc., ("HNR"), a Delaware corporation, which will operate a commercial site for the delivery of PoNS Treatment to patients with balance and gait disorders upon FDA clearance. On October 10, 2019, the Company formed Helius Canada Acquisition Ltd. ("HCA"), a company incorporated under the federal laws of Canada and a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc. ("HMC"), a company incorporated under the federal laws of Canada, which acquired Heuro Canada, Inc. ("Heuro") from Health Tech Connex Inc. ("HTC") on October 30, 2019 (see Note 2).

The Company's wholly owned subsidiaries are comprised of HMI, HMC, HCA and HNR.

The Company was incorporated in British Columbia, Canada, on March 13, 2014. On May 28, 2014, the Company completed a continuation via a plan of arrangement whereby the Company moved from being a corporation governed by the British Columbia Corporations Act to a corporation governed by the Wyoming Business Corporations Act. On July 20, 2018, the Company completed its reincorporation from Wyoming to the state of Delaware. The Company is headquartered in Newtown, Pennsylvania.

The Company's Class A common stock, par value $0.001 per share ("common stock") is listed on the Nasdaq Capital Market ("Nasdaq") and the Toronto Stock Exchange (the "TSX"). The common stock began trading on the Canadian Securities Exchange on June 23, 2014, under the ticker symbol "HSM" and the trading was subsequently transferred to the TSX on April 18, 2016. On April 11, 2018, the common stock began trading on Nasdaq under the ticker symbol "HSDT" after having traded on the OTCQB in the United States under the ticker symbol "HSDT" since February 10, 2015.

2018 Reverse Stock Split

Effective after the close of business on January 22, 2018, the Company completed a 1-for-5 reverse stock split of its common stock. All share and per share amounts herein have been reflected on a post-split basis.

2020 Reverse Stock Split

Effective after the close of business on December 31, 2020, the Company completed a 1-for-35 reverse stock split of its common stock ("2020 Reverse Stock Split"). The 2020 Reverse Stock Split did not change the par value of the Company's common stock or the number of common or preferred shares authorized by the Company's Certificate of Incorporation. All share and per-share amounts have been retrospectively adjusted to reflect the 2020 Reverse Stock Split for all periods presented.

Going Concern Uncertainty

As of December 31, 2019, the Company had cash of $5.5 million. For the year ended December 31, 2019, the Company incurred a net loss of $9.8 million and, as of December 31, 2019, its accumulated deficit was $104.8 million. For the year ended December 31, 2019, the Company had $1.5 million of revenue from the commercial sale of products or services. The Company expects to continue to incur operating losses and net cash outflows until it generates a level of revenue to support its cost structure. There is no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date of the financial statements are filed. The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business.

The Company intends to fund ongoing activities by utilizing its current cash on hand, cash received from the sale of its PoNS device in Canada and by raising additional capital through equity or debt financings. There can be no assurance that the Company will be successful in raising that additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations and planned capital expenditures.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company's reporting currency is the U.S. Dollar ("USD$").

Use of Estimates

The preparation of the consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosure of contingent assets and liabilities. Significant estimates include the assumptions used in the valuation of the significant financing component associated with revenue, fair value-pricing model for stock-based compensation and derivative financial instruments. Financial statements include estimates, which, by their nature, are uncertain. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements reflect the operations of Helius Medical Technologies, Inc. and its wholly owned subsidiaries. The usual condition for a controlling financial interest is ownership of a majority of the voting interests of an entity. However, a controlling financial interest may also exist through arrangements that do not involve controlling voting interests. As such, the Company applies the guidance of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 810 – *Consolidation* ("ASC 810"), to determine when an entity that is insufficiently capitalized or not controlled through its voting interests, referred to as a variable interest entity should be consolidated (see Note 8). All intercompany balances and transactions have been eliminated. Certain prior period amounts have been reclassified to conform to current period presentation.

Concentrations of Credit Risk

The Company is subject to credit risk with respect to its cash. Amounts invested in such instruments are limited by credit rating, maturity, industry group, investment type and issuer. The Company is not currently exposed to any significant concentrations of credit risk from these financial instruments. The Company seeks to maintain safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements and a competitive after-tax rate of return.

Receivables

Accounts receivables are stated at their net realizable value. In determining the appropriate allowance for doubtful accounts, the Company considers a combination of factors, such as the aging of trade receivables, its customers' financial strength, and payment history. Changes in these factors, among others, may lead to adjustments in the Company's allowance for doubtful accounts. The calculation of the required allowance requires judgment by Company management. As of December 31, 2019, the Company's accounts receivable of $0.4 million, is net of an allowance for doubtful accounts of $0.2 million and is the result of revenue from product sales. As of December 31, 2018, accounts receivable consisted primarily of amounts owed related to license revenue of approximately $0.5 million recognized in 2018 resulting from the Company's arrangement with HTC and Heuro, of which $0.3 million was classified as a non-current receivable. As described below, the Company modified its arrangement with HTC on October 30, 2019.

Other receivables included refunds from research and development ("R&D") tax credits of $0.2 million and Goods and Services Tax and Quebec Sales Tax refunds related to the Company's Canadian expenditures of $0.1 million as of December 31, 2019. Other receivables included refunds from research and development ("R&D") tax credits of $0.1 million as of December 31, 2018.

Inventory

The Company's inventory consists of raw materials, work in progress and finished goods of the PoNS device. Inventory is stated at the lower of cost (average cost method) or net realizable value. Adjustments to reduce the cost of inventory to its net realizable value are made if required. The Company calculates provisions for excess inventory based on inventory on hand compared to anticipated sales or usage. Management uses its judgment to forecast sales or usage and to determine what constitutes a reasonable period. There can be no assurance that the amount ultimately realized for inventories will not be materially different than that assumed in the calculation of the reserves. Inventory markdowns to net realizable value of $50 thousand were recorded during the year ended December 31, 2019.

As of December 31, 2019 and 2018, inventory consisted of the following (amounts in thousands):

	As of December 31, 2019	As of December 31, 2018
Raw materials	$ 144	$ 392
Work-in-process	375	—
Finished goods	129	—
Inventory	**$ 648**	**$ 392**
Inventory reserve	(50)	—
Total inventory, net of reserve	**$ 598**	**$ 392**

Property and Equipment

Property and equipment are carried at cost, less accumulated depreciation. Depreciation is recognized using the straight-line method over the useful lives of the related asset or the term of the related lease. Expenditures for maintenance and repairs, which do not improve or extend the expected useful life of the assets, are expensed to operations while major repairs are capitalized. The estimated useful life of its leasehold improvements is over the shorter of its lease term or useful life of 5 years, the estimated useful life of furniture and fixtures is 7 years; equipment has an estimated useful life of 15 years and computer software and hardware has an estimated useful life of 3 to 5 years.

The following tables summarizes the Company's property and equipment as of December 31, 2019 and 2018 (amounts in thousands):

	As of December 31,	
	2019	2018
Leasehold improvement	$ 182	$ 182
Furniture and fixtures	247	185
Equipment	286	219
Computer hardware and software	182	44
Property and equipment	897	630
Less accumulated depreciation	(185)	(76)
Property and equipment, net	$ 712	$ 554

Depreciation expense of $127 thousand and $59 thousand for the years ended December 31, 2019 and 2018, respectively. During 2019, the Company wrote-off $17 thousand of fully depreciated software.

Business Combinations

Transactions in which the Company obtains control of a business are accounted for according to the acquisition method as described in FASB ASC 805 – Business Combinations. The assets acquired and liabilities assumed are recognized and measured at their fair values as of the date control is obtained. Acquisition related costs in connection with a business combination are expensed as incurred. Contingent consideration is recognized and measured at fair value at the acquisition date and until paid re-measured on a recurring basis. It is classified as a liability based on appropriate GAAP.

On October 30, 2019, the Company and HTC entered into a Share Purchase Agreement (the "SPA") whereby the Company, through its wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately CAD$2.1 million (USD$1.6 million) was paid to HTC, which included (1) cash of CAD$0.5 million (USD$0.4 million), (2) delivery of 55 PoNS devices for which the fair value was determined to be CAD$0.5 million (USD$0.4 million), (3) the CAD$750 thousand (USD$0.6 million) receivable from the September 2018 strategic alliance agreement and (4) the sale of exclusivity rights granted to HTC in the Co-Promotion Agreement (as defined below) to provide PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia with a determined fair value of CAD$0.4 million (USD$0.3 million). The transaction has been accounted for as a business combination.

The operating results of Heuro have been included in the consolidated statement of operations and comprehensive loss since the date of the acquisition.

The acquisition related costs were $0.1 million and were accounted for as selling, general and administrative expenses in the consolidated statement of operations and comprehensive loss.

Supplemental proforma financial information has not been presented here because the proforma effects of this acquisition are not material to the Company's reported results for any period presented.

The following table summarizes the recognized fair values of identifiable assets acquired and liabilities assumed as of October 30, 2019:

Assets:	October 30, 2019 Fair Value
Cash and cash equivalents	$ 1
Other receivables	19
Fixed assets	7
Intangibles	564
Goodwill	1,226
Total assets	**$ 1,817**
Liabilities:	
Accounts payable	186
Other current liabilities	9
Total liabilities	**$ 195**
Net assets acquired	**$ 1,622**

The fair values assigned to identifiable intangible assets assumed were based on management's current estimates and assumptions and is considered preliminary. The Company believes that the most recent information available provides a reasonable basis for assigning fair value, but anticipates receiving additional information, and as such, the provisional measurements of fair value are subject to change. The Company will finalize the amounts recognized as it obtains the information necessary to complete the analysis, but no later than one year from the acquisition date.

Acquired intangibles consisted of customer relationships and proprietary technology. The remaining useful life at acquisition was 1.25 years and 5 years, respectively, and the acquired intangibles are amortized using the straight-line method.

Factors considered by the Company in determination of goodwill include synergies, strategic fit and other benefits that do not meet the recognition criteria of acquired identifiable intangible assets. The recognized goodwill of $1.2 million is not expected to be deductible for tax purposes.

The fair value of the 55 PoNS devices in the amount of CAD$0.5 million will be recognized as revenue within the consolidated statements of operations and comprehensive loss once control has been transferred in accordance with ASC 606. As of December 31, 2019, the control had not been transferred resulting in the fair value being recorded as deferred revenue on the consolidated balance sheet.

In connection with the SPA, on October 30, 2019, the Company entered into a Clinical Research and Co-Promotion Agreement with HTC (the "Co-Promotion Agreement"), whereby each company will promote the sales of the PoNS Treatment and the NeuroCatch™ device throughout Canada. This co-promotion arrangement terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. Also, subject to certain terms and conditions, Helius granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC will purchase the PoNS devices for use in these regions exclusively from the Company and on terms no less favorable than the then-current standard terms and conditions. This exclusivity right has an initial term of ten (10) years, renewable by HTC for one additional ten (10) year term upon sixty (60) days' written notice to Helius. The Co-Promotion Agreement had a fair value of CAD$360 thousand at the time of acquisition. License revenue will be recognized in connection with the Co-Promotion Agreement ratably over the ten year term.

Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair values underlying net assets acquired in an acquisition. All of the Company's goodwill as of December 31, 2019 is the result of the Heuro acquisition discussed above. Goodwill is not amortized, but rather will be tested annually for impairment or more frequently if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The Company will test goodwill for impairment annually in the fourth quarter of each year using data as of October 1 of that year.

Goodwill is allocated to, and evaluated for impairment at the Company's one identified reporting unit. Goodwill is tested for impairment by either performing a qualitative evaluation or a quantitative test. The qualitative evaluation is an assessment of factors to determine whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. The Company may elect not to perform the qualitative assessment for its reporting unit and perform the quantitative impairment test. The quantitative goodwill impairment test requires the Company to compare the carrying value of the reporting unit's net assets to the estimated fair value of the reporting unit.

If the estimated fair value exceeds the carrying value, no further evaluation is required, and no impairment loss is recognized. If the carrying amount of a reporting unit, including goodwill, exceeds the estimated fair value, the excess of the carrying value over the estimated fair value is recorded as an impairment loss, the amount of which is not to exceed the total amount of goodwill allocated to the reporting unit.

Definite-lived intangibles consist principally of acquired customer relationships and proprietary software as well as internally developed software. All are amortized straight-line over their estimated useful lives.

Intangible assets as of December 31, 2019 consist of the following:

		As of December 31, 2019	
	Useful Life	Gross Carrying Amount	Accumulated Amortization
Customer relationships	1.25 years	$ 423	$ (55)
Acquired proprietary software	5 years	148	(5)
Internally developed software	3 years	75	(4)
Total intangible assets		$ 646	$ (64)

Amortization expense related to the intangible assets was $64 thousand for the year ended December 31, 2019.

Amortization expense is anticipated to be as follows in future years:

For the Year Ending December 31,	
2020	$393
2021	83
2022	51
2023	30
2024	25
	$582

Internally Developed Software Costs

The Company follows ASC 350-40, Accounting for the Costs of Computer Software Developed or Obtained for Internal Use, in accounting for its internally developed software costs. Costs incurred during the preliminary

project work stage or conceptual stage, such as determining the performance requirements, system requirements and data conversion, are expensed as incurred. Costs incurred in the application development phase, such as coding, testing for new software and upgrades that result in additional functionality, are capitalized and are amortized using the straight-line method over the useful life of the software, which was determined to be three years. Amortization of these capitalized costs commences when the software becomes ready for its intended use. Costs incurred during the post-implementation stage, such as maintenance and application training, are expensed as incurred.

Leases

On January 1, 2019, the Company adopted ASU No. 2016-02, *Leases*, using the modified retrospective method. The Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed the Company to carry forward the historical lease classification. Adoption of this standard resulted in the recording of an operating lease right-of-use ("ROU") asset and corresponding operating lease liabilities of $0.7 million. The Company's condensed consolidated balance sheets for reporting periods beginning on or after January 1, 2019 are presented under the new guidance, while prior period amounts were not adjusted and continue to be reported in accordance with previous guidance.

The Company does not record an operating lease ROU asset and corresponding lease liability for leases with an expected term of twelve months or less and recognizes lease expense for these leases as incurred over the lease term. As of December 31, 2019, the Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of December 31, 2019, the Company has not entered into any additional lease arrangements. Operating lease ROU assets and operating lease liabilities are recognized upon the adoption date based on the present value of lease payments over the lease term. The Company does not have a public credit rating and as such used a corporate yield with a "CCC" rating by S&P Capital IQ with a term commensurate with the term of its lease as its incremental borrowing rate in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term. The Company's lease arrangement does not have lease and non-lease components which are to be accounted for separately. As of December 31, 2019, approximately $0.1 million of the Company's operating lease ROU asset had been amortized (see Note 7).

Foreign Currency

Prior to April 1, 2018, the Company's functional currency was the Canadian dollar ("CAD$"). Translation gains and losses from the application of the USD$ as the reporting currency during the period that the Canadian dollar was the functional currency were included as part of cumulative currency translation adjustment, which is reported as a component of stockholders' equity (deficit) as accumulated other comprehensive income (loss).

The Company re-assessed its functional currency and determined that, as of April 1, 2018, its functional currency had changed from the CAD$ to the USD$ based on management's analysis of changes in the primary economic environment in which the Company operates. The change in functional currency was accounted for prospectively from April 1, 2018 and financial statements prior to and including the period ended March 31, 2018 were not restated for the change in functional currency.

For periods commencing April 1, 2018, monetary assets and liabilities denominated in foreign currencies are translated into U.S. dollars using exchange rates in effect at the balance sheet date. Opening balances related to non-monetary assets and liabilities are based on prior period translated amounts, and non-monetary assets acquired, and non-monetary liabilities incurred after April 1, 2018 are translated at the approximate exchange rate prevailing at the date of the transaction. Revenue and expense transactions are translated at the approximate exchange rate in effect at the time of the transaction. Foreign exchange gains and losses are included in the consolidated statement of operations and comprehensive loss as foreign exchange gain (loss).

The functional currency of HMC and HCA, the Company's Canadian subsidiaries, is the CAD$ and the functional currency of HMI and HNR is the USD$. Transactions in foreign currencies are recorded into the functional currency of the relevant subsidiary at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Revenues, expenses and cash flows are translated at the weighted-average rates of exchanges for the reporting period. The resulting currency translation adjustments are not included in the Company's consolidated statements of operations and comprehensive loss for the reporting period, but rather are accumulated and gains and losses are recorded in foreign exchange gain (loss), as a component of comprehensive loss, within the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for all stock-based payments and awards under the fair value-based method. The Company recognizes its stock-based compensation expense using the straight-line method.

The Company accounts for the granting of stock options to employees and non-employees using the fair value method whereby all awards are measured at fair value on the date of the grant. The fair value of all employee stock options is expensed over the requisite service period with a corresponding increase to additional paid-in capital. Upon exercise of stock options, the consideration paid by the option holder is recorded in additional paid-in capital, while the par value of the shares received is reclassified from additional paid in capital to common stock. Stock options granted to employees are accounted for as liabilities when they contain conditions or other features that are indexed to other than a market, performance or service conditions.

Prior to the adoption of ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07")* during the third quarter of 2018, stock-based payments to non-employees were measured at the fair value of the consideration received, or the fair value of the equity instruments issued, or liabilities incurred, whichever was more reliably measurable, and the fair value of stock-based payments to non-employees was re-measured at the end of each reporting period until the counterparty performance was completed, with any change therein recognized over the vesting period of the award and in the same manner as if the Company had paid cash instead of paying with or using equity-based instruments. The fair value of the stock-based payments to non-employees that were fully vested and non-forfeitable as of the grant date was measured and recognized at that date. Following the adoption of ASU 2018-07, stock-based payments to non-employees are now being measured based on the fair value of the equity instrument issued and compensation expense for non-employee stock awards is recognized over the requisite service period following the measurement of the fair value on the grant date over the vesting period of the award.

The Company uses the Black-Scholes option-pricing model to calculate the fair value of stock options. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. Changes in these assumptions can materially affect the fair value estimate.

Awards of options that provide for an exercise price that is not denominated in: (a) the currency of a market in which a substantial portion of the Company's equity securities trades in, (b) the currency in which the employee's pay is denominated, or (c) the Company's functional currency, are required to be classified as liabilities. The change in the Company's functional currency, effective April 1, 2018 resulted in the reclassification of outstanding stock options that were previously denominated in CAD$ from equity- to liability-classified options (see Note 4). Liability classified options are re-measured to their fair values at the end of each reporting date with changes in the fair value recognized in stock-based compensation expense or additional paid-in capital until settlement or cancellation. Under FASB's ASC 718 – Compensation – Stock Compensation, when an award is reclassified from equity to liability, if at the reclassification date the original vesting conditions

are expected to be satisfied, then the minimum amount of compensation cost to be recognized is based on the grant date fair value of the original award. Fair value changes below this minimum amount are recorded in additional paid-in capital. In June 2018, the Company's Board of Directors approved subject to the consent of the holders of such options the modification of outstanding stock options with exercise prices denominated in CAD$ to convert the exercise prices of such options to USD$ based on the prevailing USD$/CAD$ exchange rates on the dates of the grants for such modified stock options. During the third quarter of 2018, employee and non-employee option holders owning stock options representing an aggregate of 78,318 shares of common stock consented to the modification. Employee stock options with a fair value of $10.3 million on August 8, 2018, which were previously classified as stock-based compensation liability, were reclassified to equity during the third quarter of 2018. Following these reclassifications, the Company no longer has any liability-classified stock options (see Note 4).

Revenue Recognition

In accordance with FASB's ASC 606, *Revenue from Contracts with Customers*, ("ASC 606"), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies the five-step model to contracts when it determines that it is probable it will collect substantially all of the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price, after consideration of variability and constraints, if any, that is allocated to the respective performance obligation when the performance obligation is satisfied.

License Revenue

Prior to the fourth quarter of 2018, the Company had not generated revenue. During the fourth quarter of 2018, as part of its exclusive strategic alliance agreement, the Company transferred a license to Heuro in order for it to develop the clinic systems to facilitate the commercialization of the PoNS Treatment in Canada. The license was a functional license as it had stand-alone functionality. As such, the Company recognized revenue once control transferred, which occurred in the fourth quarter of 2018 when regulatory approval of the PoNS device in Canada was obtained and the commercialization of the product, as defined within the agreement, began. The agreement provided to pay the Company CAD$750 thousand in three annual payments of CAD$250 thousand beginning December 31, 2019, in consideration for the exclusivity right the Company granted to Heuro. The Company considered this to be a significant financing component and as such, the amount reflected in its consolidated statements of operations and comprehensive loss was discounted. The discount rate utilized to measure revenue and the related receivable was determined based on the rate that would be reflected in a separate financing transaction with the customer. During the fourth quarter of 2018, the Company recognized revenues of $0.5 million in license fees when it satisfied its performance obligation. As described above, the Company

modified its arrangement with HTC on October 30, 2019. License revenue will be recognized ratably over the ten year term as the performance obligation is met in connection with the Co-Promotion Agreement. During the fourth quarter of 2019, the Company recognized revenues of $5 thousand in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of $0.3 million is recorded as deferred revenue on the consolidated balance sheet.

Product Sales, net

During the first half of 2019, product sales were derived from the sale of the PoNS device and certain support services including services from the use of the NeuroCatch™ device, which is owned by HTC and assesses electroencephalogram brain waves related to cognition of patients participating in the PoNS Treatment at neuroplasticity clinics in Canada. The Company acted in an agency capacity for services performed using the NeuroCatch device and remitted CAD$600 for each patient assessed with the NeuroCatch device. According to the supply agreement with each of these clinics, the Company's performance obligation was met when it delivered the PoNS device to the clinic's facility and the clinic assumed title of the PoNS device upon acceptance. As such, revenue is recognized at a point in time. Shipping and handling costs associated with outbound freight before control of a product has been transferred to a customer are accounted for as a fulfillment cost and are included in cost of sales. Further, according to the Company's arrangement with HTC and Heuro, the Company shared 50/50 with Heuro in fees from support services excluding the CAD$600 payment for an assessment using the NeuroCatch device. Subsequent to July 1, 2019, product sales were derived from the sale of the PoNS device alone as the NeuroCatch is sold directly to the neuroplasticity clinics in Canada by HTC. For the year ended December 31, 2019, the Company recorded $1.5 million in product sales net of $11 thousand for HTC's portion related to assessments using the NeuroCatch device. As described above, the Company modified its arrangement with HTC on October 30, 2019. As of December 31, 2019, the control of the 55 PoNS devices included as consideration in the Heuro acquisition had not been transferred resulting in the fair value of the devices being recorded as deferred revenue of $0.4 million on the consolidated balance sheet. Revenue will be recognized for these devices as control is transferred. The only returns during 2019 were the result of warranty returns for defective products. These returns were insignificant during the year and any future replacements are expected to be immaterial.

Fee Revenue

During the first half of 2019, the Company's agreement with HTC and Heuro also entitled the Company to 50% of the franchise fees collected by Heuro from each franchise agreement Heuro executed with neuroplasticity clinics engaged in providing the PoNS Treatment. For the year ended December 31, 2019, the Company recognized $37 thousand as its 50% portion of the franchise fees. There were 3 franchise agreements entered into for the year ended December 31, 2019, all of which occurred in the first half of the year.

As of December 31, 2019, the Company had recorded $0.2 million in current receivables, net and had no contract assets or liabilities on its consolidated balance sheets related to the supply agreements with each clinic. As of December 31, 2019, the Company did not have any receivables on its consolidated balance sheets related to license revenue pursuant to the Company's arrangement with HTC and Heuro due to the modification of its arrangement with HTC on October 30, 2019. As of December 31, 2018, the Company has recorded $0.2 million and $0.3 million in current and non-current receivables, respectively, and had no contract assets or liabilities on its consolidated balance sheets related to license revenue pursuant to the Company's arrangement with HTC and Heuro.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, royalty expenses, freight charges, customs duties, wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling the Company's sales orders and certain support services provided by Heuro on the Company's behalf.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The asset and liability method provide that deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company records a valuation allowance to reduce deferred tax assets to the amount that is believed more likely than not to be realized.

The Company has adopted the provisions of ASC 740 *Income Taxes* regarding accounting for uncertainty in income taxes. The Company initially recognizes tax positions in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of the tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts. Application requires numerous estimates based on available information. The Company considers many factors when evaluating and estimating its tax positions and tax benefits. These periodic adjustments may have a material impact on the consolidated statements of operations and comprehensive loss. When applicable, the Company classifies penalties and interest associated with uncertain tax positions as a component of income tax expense in its consolidated statements of operations and comprehensive loss.

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, development and manufacturing of clinical trial devices and devices for manufacturing testing and materials and supplies as well as regulatory costs related to post market surveillance, quality assurance complaint handling and adverse event reporting. R&D costs are charged to operations when they are incurred.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates and manages its business within one operating and reportable segment. Accordingly, the Company reports the accompanying consolidated financial statements in the aggregate in one reportable segment.

Derivative Financial Instruments

The Company evaluates its financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815, *Derivatives and Hedging*. The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the condensed consolidated statements of operations and comprehensive loss. As of December 31, 2019 and 2018, the Company's derivative financial instruments were comprised of warrants issued in connection with both public and/or private securities offerings. During the third quarter of 2018, the non-employee stock options were reclassified to equity following the modification of these stock options. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and the fair value of the underlying instrument is reclassified to equity (see Note 4).

The classification of derivative financial instruments, including whether such instruments should be recorded as liabilities/assets or as equity, is reassessed at the end of each reporting period. Derivative financial instruments

that become subject to reclassification are reclassified at the fair value of the instrument on the reclassification date. Derivative financial instruments will be classified in the consolidated balance sheet as current if the right to exercise or settle the derivative financial instrument lies with the holder.

Fair Value Measurements

The Company accounts for financial instruments in accordance with ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"). ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The Company's financial instruments recorded in its consolidated balance sheets consist primarily of cash, receivables, accounts payable, accrued liabilities, and derivative financial instruments. The book values of these instruments, with the exception of derivative financial instruments and non-current receivables, approximate their fair values due to the immediate or short-term nature of these instruments.

The Company's derivative financial instruments are classified as Level 3 within the fair value hierarchy and required to be recorded at fair value on a recurring basis. Unobservable inputs used in the valuation of these financial instruments include volatility of the underlying share price and the expected term. See Note 3 for the inputs used in the Black-Scholes option-pricing model as of December 31, 2019 and 2018 and the roll forward of the derivative financial instruments. The Company's derivative financial instruments are comprised of warrants which are classified as liabilities.

The following table summarizes the Company's derivative financial instruments and stock-based compensation liability within the fair value hierarchy as of December 31, 2019 and 2018 (amounts in thousands):

	Fair Value	Level 1	Level 2	Level 3
December 31, 2019				
Liabilities:				
Derivative financial instruments	$ 5	$ —	$ —	$ 5
December 31, 2018				
Assets:				
Non-current receivable	$ 294	$ —	$ —	$ 294
Liabilities:				
Derivative financial instruments	$ 13,769	$ —	$ —	$13,769

There were no transfers between any of the levels during the years ended December 31, 2019 and 2018.

Basic and Diluted Income (Loss) per Share

Earnings or loss per share ("EPS") is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted EPS is computed by dividing net income (loss) by the weighted average of all potentially dilutive shares of common stock that were outstanding during the periods presented.

The treasury stock method is used in calculating diluted EPS for potentially dilutive stock options and share purchase warrants, which assumes that any proceeds received from the exercise of in-the-money stock options and share purchase warrants, would be used to purchase common shares at the average market price for the period, unless including the effects of these potentially dilutive securities would be anti-dilutive.

The basic and diluted loss per share for the periods noted below is as follows (amounts in thousands, except for share and per share amounts):

	For the Year Ended December 31,	
	2019	2018
Basic and Diluted		
Numerator		
Net loss	$ (9,781)	$ (28,623)
Denominator		
Weighted-average common shares outstanding – basic and diluted	752,932	651,034
Basic and diluted net loss per share	$ (12.99)	$ (43.97)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the periods noted below, as they would have been anti-dilutive due to the Company's losses for the years ended December 31, 2019 and 2018 and because the exercise price of certain of these outstanding securities were greater than the average closing price of the Company's common stock.

	For the Year Ended December 31,	
	2019	2018
Options outstanding	99,018	94,475
RSUs	788	27
Warrants outstanding	86,958	114,406
Total	186,764	208,908

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held and requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which amends the effective date of ASU 2016-13. Public business entities that meeting the definition of an SEC filer, excluding entities eligible to be a Small Reporting Company ("SRC") as defined by the SEC, are required to adopt the standard for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are required to adopt the standard for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company meets the definition of an SRC and therefore the standard will not be effective until the beginning of 2023. The Company is evaluating the effect that ASU 2016-13 will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. The Company will adopt the standard as of January 1, 2020 and anticipates an increase in Level 3 fair value disclosures within the footnotes to the consolidated financial statements.

In November 2018, FASB issued ASU 2018-18, C*ollaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606,* which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company will adopt the standard as of January 1, 2020. In conjunction with the acquisition of Heuro on October 30, 2019, the Company entered into a co-promotion agreement with HTC which meets the definition of a collaborative agreement. Certain components of the co-promotion agreement fall under the scope of ASC 606 and will be accounted for accordingly.

3. COMMON STOCK AND WARRANTS

On June 28, 2018, at the Company's 2018 Annual Meeting of Shareholders, the Company's shareholders approved the Company's reincorporation from the state of Wyoming to the state of Delaware. On July 20, 2018, the Company completed its reincorporation from Wyoming to the state of Delaware.

As a result, following the Company's reincorporation, the Company's authorized capital stock pursuant to its Delaware charter consists of 150,000,000 authorized shares of common stock, at a par value per share of $0.001 and 10,000,000 authorized shares of preferred stock at a par value per share of $0.001. Holders of common stock are entitled to vote at any meeting of the Company's stockholders on the basis of one vote per share of common stock owned as of the record date of such meeting. Each share of common stock entitles the holder to receive dividends, if any, as declared by the Company's Board of Directors.

No dividends have been declared since inception of the Company through December 31, 2019. In the event of a liquidation, dissolution or winding-up of the Company, other distribution of assets of the Company among its stockholders for the purposes of winding-up its affairs or upon a reduction of capital, the stockholders shall, share equally, share for share, in the remaining assets and property of the Company.

On April 18, 2016, the Company closed its short form prospectus offering in Canada and a concurrent U.S. private placement (the "April 2016 Offering") of units (the "Units") with gross proceeds to the Company of $7.2 million through the issuance of Units at a price of CAD$175.00 per Unit. Each Unit consists of one share of common stock in the capital of the Company (a "Common Share') and one-half of one Common Share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitled the holder thereof to acquire one additional Common Share at an exercise price of CAD$262.50 on or before April 18, 2019. Mackie Research Capital Corporation (the "Agent") acted as agent and sole bookrunner in connection with the April 2016 Offering. The Company paid the Agent a cash commission of $0.3 million and granted to the Agent compensation options exercisable to purchase 2,491 Units at an exercise price of CAD$175.00 per Unit for a period of 24 months from the closing of the April 2016 Offering. The Company incurred other cash issuance costs of $1.1 million related to this offering. During the year ended December 31, 2019, 1,096 warrants were exercised. On April 18, 2019, 26,352 warrants were cancelled due to their expiration.

On May 2, 2016, the Company closed the sale of the additional units issued pursuant to the exercise of the over-allotment option granted to the Agent in connection with the April 2016 Offering. The April 2016 Offering was made pursuant to a short form prospectus filed with the securities regulatory authorities in each of the provinces of Canada, except Québec. Pursuant to the exercise of the over-allotment option, the Company issued an additional 6,229 units at a price of CAD$175.00 per unit for additional gross proceeds to the Company of $0.9 million, bringing the total aggregate gross proceeds to the Company under the Offering to $8.1 million. Each over-allotment unit consisted of one share of common stock in the capital of the Company and one-half of one Common Share purchase warrant. Each over-allotment warrant entitles the holder thereof to acquire one additional over-allotment Common Share at an exercise price of CAD$262.50 on or before April 18, 2019. In connection with the closing of the over-allotment option, the Company paid the Agent a cash commission of $0.1 million and granted to the Agent compensation options exercisable to purchase 373 over-allotment units at an exercise price of CAD$175.00 per unit for a period of 24 months from the over-allotment closing. As of December 31, 2018, all remaining outstanding compensation options had been cancelled due to their expiration.

For the year ended December 31, 2018, the Company recorded a $0.1 million gain in change in fair value of derivative financial instruments due to the expiration of both the April 18, 2016 and May 2, 2016 compensations options.

The proceeds from the April 2016 Offering were allocated on a relative fair value basis between the common stock and the warrants issued. The warrants issued in connection with the April 2016 Offering were classified within equity in the Company's consolidated balance sheets. These warrants were recorded in additional paid-in capital in the Company's consolidated balance sheets at their fair value. As discussed in Note 1, due to the change in the Company's functional currency, as of April 1, 2018, these warrants were reclassified to liabilities as derivative financial instruments on the Company's consolidated balance sheet as they are now priced in a currency other than the Company's functional currency. This resulted in the Company recording a $4.7 million increase in derivative financial instruments and a $1.4 million reduction in additional paid-in capital on its consolidated balance sheet and a $3.3 million loss related to the change in fair value of derivative financial instruments on its consolidated statement of operations and comprehensive loss during the year ended December 31, 2018.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the April 2016 Offering using the Black-Scholes option pricing model as of the grant date and as of April 1, 2018 and December 31, 2018:

	December 31, 2018	April 1, 2018	Grant Date
Stock price	CAD$ 448.00	CAD$450.45	CAD$190.75
Exercise price	CAD$ 262.50	CAD$262.50	CAD$262.50
Warrant term	0.30 years	1.05 years	3.0 years
Expected volatility	83.56%	71.13%	83.83%
Risk-free interest rate	1.64%	1.60%	0.60%
Dividend rate	0.00%	0.00%	0.00%

On February 16, 2017, the Company completed an underwritten registered public offering and issued an aggregate of 37,457 shares of common stock for gross proceeds of $9.2 million. The Company incurred cash issuance costs of $1.2 million in connection with this offering.

In June 2017, the Company completed a non-brokered private placement of 22,857 shares of common stock for gross proceeds of $5.4 million. The Company incurred approximately $9 thousand in share issuance cost related to the private placement.

In December 2017, the Company completed a three-tranche non-brokered private placement (the "December 2017 financing") for an aggregate of 18,457 units for gross proceeds of approximately $6.3 million. Each unit consisted of one share of common stock and one share purchase warrant, and was sold at a price of $343.00 per unit. Each warrant entitles the holder to acquire one additional share of common stock and is exercisable over a period of 36 months following the respective closing of the December 2017 financing at an exercise price of $428.75 per warrant share. The first tranche, which closed on December 22, 2017, was for 7,740 units for which the Company received gross proceeds of approximately $2.6 million. The second tranche, which closed on December 28, 2017, was for 4,886 units for which the Company received approximately $1.7 million, while the third tranche, which closed on December 29, 2017, was for 5,830 units for which the Company received $2.0 million. The Company paid $0.1 million in share issuance costs related to the December 2017 financing.

As a result of the change in the Company's functional currency, these warrants have been reclassified from liabilities as derivative financial instruments to additional paid-in capital in the Company's consolidated balance sheet. As of April 1, 2018, $2.5 million, was reclassified from derivative financial instruments to additional paid-in capital, representing the fair value of warrants having USD$ exercise prices. There was no impact to the

Company's consolidated statement of operations and comprehensive loss as a result of this reclassification as the fair value of these warrants on April 1, 2018, was the same as of March 31, 2018, the most recent date that the fair value of these warrants was re-measured.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the December 2017 financing using the Black-Scholes option pricing model as of the grant dates and on April 1, 2018.

	April 1, 2018	December 29, 2017	December 28, 2017	December 22, 2017
Stock price	$ 353.85	$ 431.20	$ 435.75	$ 371.00
Exercise price	$ 428.75	$ 428.75	$ 428.75	$ 428.75
Warrant term	2.7 years	3.0 years	3.0 years	3.0 years
Expected volatility	65.40%	60.24%	60.24%	60.24%
Risk-free interest rate	2.39%	1.98%	2.00%	2.01%
Dividend rate	0.00%	0.00%	0.00%	0.00%

On April 13, 2018, the Company issued 61,197 shares of its common stock and warrants to purchase 61,197 shares of the Company's common stock in an underwritten public offering at a price of $261.45 per share and accompanying warrant. Gross proceeds from the offering were approximately $16.0 million. On April 24, 2018, the Company closed on the sale of an additional 9,179 shares of its common stock and warrants pursuant to the exercise of the over-allotment option (collectively the "April 2018 offering") granted to the underwriters in connection with the offering at a price of $261.45 per share and accompanying warrants. Gross proceeds from the exercise of the over-allotment option was $2.4 million. BTIG, LLC and Echelon Wealth Partners acted as joint book-running managers for the April 2018 Offering. The Company paid approximately $1.1 million in underwriting discounts and commissions and incurred offering expenses of approximately $1.0 million in connection with the April 2018 Offering, resulting in net proceeds of $16.3 million from the April 2018 offering. The underwriting discounts and commissions and offering expenses were allocated between share issuance costs and expenses based on the relative fair values of common stock and warrants issued in connection with the April 2018 Offering, resulting in the recording of approximately $0.8 million of expenses in the Company's consolidated statement of operations and comprehensive loss. The fair value of these warrants at issuance was approximately $7.4 million.

Each warrant issued in connection with the April 2018 offering entitles the holder to acquire one additional share of common stock at an exercise price of CAD$428.75 per share on or before April 10, 2021. Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the April 2018 offering should be accounted for as liabilities as the ability to maintain an effective registration is outside of the Company's control and that it may be required to settle the exercise of the warrants in cash and because, as a result of the change in the Company's functional currency (see Note 2), the exercise prices of these warrants are in a currency other than the Company's functional currency. Consequently, the Company determined the fair value of each warrant issuance using the Black-Scholes option-pricing model, with the remainder of the proceeds allocated to the common shares. As of December 31, 2019, 2,025 warrants had been exercised, all during 2018, for gross proceeds of CAD$0.9 million.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the April 2018 Offering using the Black-Scholes option pricing model as of the date of the initial closing of the offering and the date of the closing of the over-allotment option, as well as of December 31, 2019.

	December 31, 2019	April 24, 2018	April 13, 2018
Stock price	CAD $ 43.05	CAD $376.60	CAD $ 344.75
Exercise price	CAD $ 428.75	CAD $428.75	CAD $ 428.75
Warrant term	1.28 years	3.00 years	3.00 years
Expected volatility	72.43%	64.49%	64.20%
Risk-free interest rate	1.72%	2.02%	1.99%
Dividend rate	0.00%	0.00%	0.00%

On November 19, 2018, the Company issued 60,606 shares of its common stock in an underwritten public offering at a price of $288.75 per share. Gross proceeds from the offering were $17.5 million. On November 2018, the Company closed on the sale of an additional 9,090 shares of its common stock pursuant to the exercise of the over-allotment option (collectively the "November 2018 offering") granted to the underwriters in connection with the offering at a price of $288.75 per share. Gross proceeds from the exercise of the over-allotment option was $2.6 million. BTIG LLC and Oppenheimer & Co acted as joint book-running managers for the November 2018 offering. The Company paid approximately $1.2 million in underwriting discounts and commissions and incurred offering expenses of approximately $0.7 million, of which $0.1 million was accrued as of December 31, 2018, resulting in net proceeds of $18.3 million.

On November 22, 2019, the Company issued 137,571 shares of its common stock in an underwritten public offering at a price of $12.25 per share. Gross proceeds from the offering (the "November 2019 Offering") were approximately $1.7 million. HC Wainwright acted as book-running manager for the November 2019 Offering. The Company paid approximately $0.1 million in underwriting discounts and commissions and incurred offering expenses of approximately $0.5 million, resulting in net proceeds of $1.1 million, in connection with the November 2019 Offering.

The following table summarizes the activities of warrants that the Company accounts for as liabilities and records as derivative financial instruments for the years ended December 31, 2019 and 2018 (amounts in thousands):

	Year Ended December 31, 2019	2018
Fair value of warrants at beginning of year	$ 13,769	$ 6,941
Issuance of warrants	—	7,372
Exercise of warrants	(35)	(3,012)
Fair value of previously classified equity warrants	—	5,049
Fair value of previously classified liability warrants reclassified to additional paid-in capital	—	(2,478)
Foreign exchange losses (gains)	384	(872)
Change in fair value of warrants during the year	(14,113)	769
Fair value of warrants at end of year	$ 5	$ 13,769

These warrants, which are classified as derivative financial instruments in the Company's consolidated balance sheets are required to be re-measured at each reporting period, with the change in fair value recorded as a gain or loss in the change of fair value of derivative financial instruments, included in other income (expense) in the Company's consolidated statements of operations and comprehensive loss. The fair value of the warrants will continue to be classified as a liability until such time as they are exercised, expire or there is an amendment to the respective agreements that renders these financial instruments to be no longer classified as such.

The fair value of all warrants classified as derivative financial instruments outstanding as of December 31, 2019 and 2018 were estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

	As of December 31,	
	2019	2018
Stock price	CAD $ 43.05	CAD$448.00
Exercise price	CAD $ 428.75	CAD$381.15
Warrant term	1.28 years	1.71 years
Expected volatility	72.43%	75.31%
Risk-free interest rate	1.72%	1.80%
Dividend rate	0.00%	0.00%

The following is a summary of warrant activity during the years ended December 31, 2019 and 2018:

	Number of Warrants (by currency denomination of exercise price)		Weighted-Average Exercise Price	
	CAD$	USD$	CAD$	USD$
Outstanding as of December 31, 2017	28,900	38,382	$258.30	$358.75
Granted	70,766	—	427.70	—
Expired	(648)	(3,901)	175.00	525.00
Exercised	(3,219)	(15,874)	345.80	236.25
Outstanding as of December 31, 2018	95,799	18,607	$381.15	$428.40
Granted	—	—	—	—
Cancelled/Expired	(26,352)	—	262.50	—
Exercised	(1,096)	—	262.50	—
Outstanding and exercisable as of December 31, 2019	68,351	18,607	$428.75	$428.40

The following table summarizes the Company's warrants outstanding and exercisable as of December 31, 2019:

Number of Warrants Outstanding	Exercise Price	Expiration Date
108	US$376.25	June 26, 2020
43	US$376.25	July 17, 2020
7,740	US$428.75	December 22, 2020
4,886	US$428.75	December 28, 2020
5,830	US$428.75	December 29, 2020
68,351	CAD$428.75	April 21, 2021
86,958		

4. SHARE BASED PAYMENTS

On May 15, 2018, the Company's Board of Directors authorized and approved the adoption of the 2018 Omnibus Incentive Plan ("2018 Plan"), under which an aggregate of 153,031 shares may be issued. This share reserve is the sum of 85,714 new shares, plus the remaining 67,317 shares that remained available for issuance under the Company's 2016 Omnibus Incentive Plan, the predecessor incentive plan (the "2016 Plan") at the time of the adoption of the 2018 Plan. Pursuant to the terms of the 2018 Plan, the Company is authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units ("RSU"), stock equivalent units and performance-based cash awards. These awards may be granted to directors, officers, employees and eligible consultants. Vesting and the term of an option is determined at the discretion of the Company's Board of Directors. Subsequent to the adoption of the 2018 Plan, the Company ceased granting

awards under the 2016 Plan, the predecessor incentive plan. However, outstanding stock options granted prior to the effective date of the 2018 Plan are still governed by the 2016 Plan or the Company's 2014 Stock Incentive Plan, which preceded the 2016 Plan.

As of December 31, 2019, there were an aggregate of 116,250 shares of common stock remaining available for grant under the Company's 2018 Plan.

For the year ended December 31, 2019, the Company issued 33,337 stock options to employees and directors of which 3,963 were forfeited. The Company did not issue any stock options to consultants.

The following is a summary of stock option activity for the year ended December 31, 2019 and 2018:

	Number of Options	Weighted Average Exercise Price in USD$	Aggregate Intrinsic Value in USD$
Outstanding as of December 31, 2017	69,921		
Granted	28,896	354.20	
Forfeited	(1,528)	346.15	
Exercised (1)	(2,814)	108.50	
Outstanding as of December 31, 2018	94,475	$ 249.87	$ 8,308
Granted	33,337	$ 162.74	
Forfeited/Cancelled	(13,939)	298.55	
Exercised (2)	(14,855)	96.95	
Outstanding as of December 31, 2019	99,018	$ 236.63	$ —
Exercisable as of December 31, 2019	53,850	$ 248.25	$ —

(1) For the year ended December 31, 2018, 242 stock options were exercised on a cashless basis resulting in 93 shares being withheld in satisfaction of the exercise price.
(2) For the year ended December 31, 2019, 14,855 stock options were exercised on a cashless basis resulting in 13,818 shares being withheld in satisfaction of the exercise price.

Upon the change in the Company's functional currency effective April 1, 2018, stock options previously classified as equity were classified as liabilities. On April 1, 2018, these options had a fair value of approximately $10.0 million, which was recorded as stock-based compensation liability in the Company's consolidated balance sheet, of which approximately $4.2 million was reclassified from additional paid-in capital and the remainder was recorded as additional stock-based compensation expense in the Company's consolidated statement of operations and comprehensive loss. In June 2018, the Company's Board of Directors' approved the modification of all outstanding stock options with exercise prices denominated in CAD$ to convert the exercise prices of such options to USD$, subject to the consent of the holders of such options. On August 8, 2018, following the consent of option holders, the Company re-measured stock options for which all holders had consented to the modification and recorded $0.3 million reduction to stock-based compensation liability and reclassified $10.3 million from liability to equity. The incremental expense as a result of the modification was immaterial to the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2018.

The following table summarizes stock options outstanding and exercisable by employees and directors as of December 31, 2019:

Number of Options Outstanding	Expiration Date	Options Outstanding Remaining Contractual Life (In Years)	Exercise Price	Fair Value Post Modification (1)	Grant Date Fair Value	Number of Options Exercisable
571	December 8, 2024	4.94	$445.20	$ 76.30	$ —	571
2,285	December 8, 2024	4.94	$445.20	$ 76.30	$ —	2,285
571	March 16, 2025	5.20	$438.20	$ 85.05	$ —	571
4,285	October 21, 2025	5.80	$112.00	$ 230.00	$ —	4,285
570	December 31, 2025	6.00	$156.80	$ 204.94	$ —	570
16,997	July 13, 2026	6.53	$187.25	$ 181.32	$ —	16,997
571	August 8, 2026	6.60	$174.30	$ 189.75	$ —	571
17,624	April 17, 2027	7.29	$284.55	$ 263.85	$ —	8,812
175	May 18, 2027	7.37	$257.25	$ 166.27	$ —	175
285	May 18, 2027	7.37	$257.25	$ 267.77	$ —	142
571	August 8, 2027	7.60	$363.30	$ 258.17	$ —	286
571	April 9, 2028	8.27	$316.05	$ 280.33	$ —	143
9,639	May 15, 2028	8.37	$384.65	$ 276.29	$ —	5,238
1,584	August 22, 2028	8.64	$358.05	$ —	$ 252.39	396
11	September 4, 2028	8.67	$356.65	$ —	$ 251.63	11
1,428	September 10, 2028	8.69	$361.90	$ —	$ 255.45	357
1,428	September 24, 2028	8.73	$339.85	$ —	$ 237.58	357
2,142	October 15, 2028	8.79	$306.25	$ —	$ 216.82	2,142
285	October 29, 2028	8.82	$339.85	$ —	$ 240.32	71
143	November 19, 2028	8.88	$280.00	$ —	$ 198.12	143
214	January 22, 2029	9.06	$267.75	$ —	$ 185.50	—
214	February 4, 2029	9.09	$254.10	$ —	$ 176.05	—
15,528	March 28, 2029	9.23	$236.60	$ —	$ 161.70	2,532
6,137	August 7, 2029	9.60	$ 71.05	$ —	$ 47.95	—
1,142	August 19, 2029	9.63	$ 67.55	$ —	$ 45.50	—
4,285	September 23, 2029	9.72	$ 60.55	$ —	$ 42.00	—
856	September 30, 2029	9.74	$ 57.75	$ —	$ 38.85	—
570	October 1, 2029	9.75	$ 58.80	$ —	$ 34.30	—
428	October 14, 2029	9.78	$ 50.75	$ —	$ 34.30	—
91,110						46,655

(1) Reflects fair value of modified stock options on August 8, 2018

As of December 31, 2019, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors was $6.0 million which will be recognized over a weighted-average remaining vesting period of 2.8 years. The Company recognizes compensation expense for only the portion of awards that are expected to vest.

During the fourth quarter of 2017, upon a review of the Company's equity compensation awards granted under the 2016 Plan, the Company determined that it had inadvertently exceeded the annual per-person sub-limits involving an option award previously granted to a current executive officer. The aggregate amount of common stock represented by this excess award was 1,714 shares. This excess award was deemed to have been granted outside of the 2016 Plan and, as such, the Company applied liability accounting to the award. As a result, this excess award was to be re-measured at the end of each reporting period until such time that the Company's stockholders approved the excess award, at which time the liability would be reclassified to equity. On June 28,

2018, the Company's stockholders approved the excess award. On August 8, 2018, upon the modification of the exercise price of this stock option to convert such exercise price from CAD$ to USD$ as described above this excess award was re-measured again and reclassified from liability to equity for the portion of the option that had vested.

For the years ended December 31, 2019 and 2018, the Company granted 33,337 and 28,468 stock options, respectively, to employees and directors at a weighted average exercise price of $162.74 and $354.20, respectively. The fair value of employee and director stock options granted for the years ended December 31, 2019 and 2018 had a weighted average grant date fair value of $105.38 and $272.30 per option, respectively, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,	
	2019	2018
Stock price	$ 162.74	$ 392.35
Exercise price	$ 162.74	$ 354.20
Expected term	5.42 years	6.25 years
Expected volatility	76.90%	78.99%
Risk-free interest rate	1.96%	2.67%
Dividend rate	0.00%	0.00%

Non-Employee Stock Options

For the year ended December 31, 2019, the Company did not grant any stock options to consultants. For the year ended December 31, 2018 the Company granted 428 stock options to consultants at a weighted average exercise price of $358.05. Stock options granted to the Company's consultants for the year ended December 31, 2018 had a weighted average grant date fair value of $310.45 per share, and they were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,
	2018
Stock price	$ 358.05
Exercise price	$ 358.05
Option term	10 years
Expected volatility	90.17%
Risk-free interest rate	2.82%
Dividend rate	0.00%

The following table summarizes stock options outstanding and exercisable by consultants as of December 31, 2019:

Number of Options Outstanding	Expiration Date	Options Outstanding Remaining Contractual Life (In Years)	Exercise Price	Fair Value Post Modification (1)	Grant Date Fair Value	Number of Options Exercisable
855	December 8, 2024	4.94	$445.20	$ 76.30	$ —	855
3,142	October 28, 2025	5.82	$111.30	$ 230.67	$ —	3,142
2,056	October 3, 2026	6.75	$180.25	$ 187.25	$ —	2,056
571	May 18, 2027	7.37	$257.25	$ 267.77	$ —	286
428	August 8, 2027	7.60	$363.30	$ 258.17	$ —	214
428	November 6, 2027	7.84	$567.00	$ 244.32	$ —	214
428	August 22, 2028	8.64	$358.05	$ —	$ 310.28	428
7,908						7,195

(1) Reflects fair value of modified stock options on August 8, 2018

As of December 31, 2019, the unrecognized compensation cost related to non-vested stock options outstanding for consultants was $0.1 million which will be recognized over a weighted-average remaining vesting period of 1.6 years.

During the third quarter of 2018, following the redenomination of the exercise prices of stock options from CAD$ to USD$, stock options awarded to consultants that are performing services for NHC ceased to be accounted for as derivative financial instruments. As a result, following the re-measurement of stock options granted to the Company's consultants on August 8, 2018, all vested stock options granted to these consultants were reclassified from liability to equity.

The following table summarizes non-employee stock options that had been accounted for as derivative financial instruments during the year ended December 31, 2018 (amounts in thousands):

	Year Ended December 31, 2018
Fair value of non-employee stock options at beginning of year	$ 2,637
Exercise of non-employee options	(737)
Cancelled	—
Foreign exchange gains	(38)
Change in fair value of non-employee stock options during the year	(656)
Reclassification to additional paid-in capital	(1,206)
Fair value of non-employee stock options at end of year	$ —

The fair value of non-employee stock options previously classified as liabilities and recorded as derivative financial instruments which were subsequently reclassified to equity following the modification of stock option previously on August 8, 2018 were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions as of August 8, 2018:

	August 8, 2018
Stock price	CAD$424.90
Exercise price	CAD$153.30
Expected life	0.93 years
Expected volatility	73.18%
Risk-free interest rate	1.95%
Dividend rate	0.00%

Restricted Stock Units

During the second quarter of 2017, the Company granted RSUs to certain employees under the 2016 Plan that were scheduled to vest over a three-year period, with 25% vesting immediately. The fair value of the RSUs was based on the closing price of the Company's common stock on the date of grant.

During the fourth quarter of 2019, certain members of the Company's executive management team elected to receive RSUs in lieu of cash compensation under the 2018 Plan that vested upon issuance. The fair value of the RSUs was based on the closing price of the Company's common stock on the day of the grant.

The following is a summary of the Company's RSU activity for the years ended December 31, 2019 and 2018:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding as of January 1, 2018	54	CAD$ 350.00
Vested and settled during 2018 (1)	(27)	CAD$ 350.00
Outstanding as of December 31, 2018	27	CAD$ 350.00
Granted	788	USD$ 21.17
Vested and settled during 2019 (1)	(27)	CAD$ 350.00
Outstanding as of December 31, 2019	788	USD$ 21.17

(1) Includes 7 RSUs withheld to satisfy required withholding taxes.

Stock-based compensation expense is classified in the Company's consolidated statements of operations and comprehensive loss as follows (amounts in thousands):

	2019	2018
Research and development	$ 898	$ 939
General and administrative	3,793	7,156
Total	$4,691	$8,095

5. ACCRUED EXPENSES

Accrued expenses consisted of the following (amounts in thousands):

	As of December 31,	
	2019	2018
Employees benefits	$ 722	$ 876
Professional services	67	518
Legal expense	81	253
Royalty fees	13	—
Franchise fees	28	—
Rent	—	98
Severance	606	66
Other	2	1
	$1,519	$1,812

6. INCOME TAXES

The components of net loss (income) are as follows (amounts in thousands):

	Year Ended December 31,	
	2019	2018
U.S.	$7,980	$29,013
Non-U.S.	1,801	(390)
	$9,781	$28,623

A reconciliation of the income tax provision computed at statutory rates to the reported income tax provision is as follows (amounts in thousands):

	Year Ended December 31,	
	2019	2018
Statutory tax rate	21.00%	21.00%
Net loss before income taxes	$ 9,781	$28,623
Expected income tax recovery	$(2,054)	$ (6,011)
Increase (decrease) in income tax recovery resulting from:		
Derivative liability	(2,964)	877
Share based payments	949	1,279
Other permanent difference	(213)	(376)
Foreign income taxed at foreign rate	(99)	23
Increase in valuation allowance	4,381	4,208
Income tax expense	$ —	$ —

The significant components of the Company's deferred income tax assets and liabilities after applying enacted corporate tax rates are as follows (amounts in thousands):

	As of December 31,	
	2019	2018
Deferred income tax assets (liabilities)		
Operating losses carried forward	$ 21,318	$ 16,028
Tax credits	679	1,217
Stock compensation	1,496	1,447
Other	1,293	85
Valuation allowance	(24,786)	(18,777)
Net deferred income tax asset	$ —	$ —

As of December 31, 2019, the Company has accumulated non-capital losses totaling $3.6 million in Canada and net operating losses of $75.3 million in the United States, which may be available to carry forward and offset future years' taxable income. The losses expire in various amounts starting in 2033.

Under the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), the net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Section 382 of the Code, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

On December 22, 2017, the U.S. Government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act ("The Act"). The Act makes broad changes to the U.S. tax code, including, but not limited to, (i) reducing the U.S federal corporate tax rate from 35% to 21%; (ii) eliminating the corporate alternative minimum tax; (iii) creating a new limitation on deductible interest expense; (iv) creating the base erosion and anti-abuse tax, a new minimum tax; (v) limitation on the deductibility of certain executive compensation; (vi) enhancing the option to claim accelerated depreciation deductions on qualified property, and (vii) changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017. The Act reduced the corporate tax rate to 21%, effective January 1, 2018.

The Company completed its determination of the accounting implications of The Act on its tax accruals as of December 31, 2018 and made estimates primarily comprised of the re-measurement of federal net deferred tax assets resulting from the permanent reduction in the U.S. statutory corporate tax rate to 21% from 34%.

Uncertain Tax Positions

The Company has adopted certain provisions of ASC 740, "Income Taxes", which prescribes a recognition threshold and measurement attribute for the recognition and measurement of tax positions taken or expected to be taken in income tax returns. The provisions also provide guidance on the de-recognition of income tax assets and liabilities, classification of current and deferred income tax assets and liabilities, and accounting for interest and penalties associated with tax positions.

The Company files income tax returns in the U.S. federal jurisdiction, and in various state and foreign jurisdictions. The Company's tax returns are subject to tax examinations by U.S. federal and state tax authorities, or examinations by foreign tax authorities until the expiration of the respective statutes of limitation. The Company currently has no tax years under examination.

As of December 31, 2019, the Company does not have an accrual relating to uncertain tax positions. It is not anticipated that unrecognized tax benefits would significantly increase or decrease within 12 months of the reporting date.

7. COMMITMENTS AND CONTINGENCIES

(a) On January 22, 2013, the Company entered into a license agreement with Advanced NeuroRehabilitation, LLC ("ANR") for an exclusive right on ANR's patent pending technology, claims and knowhow. In addition to the issuance of 91,628 shares of common stock, the Company agreed to pay a 4% royalty on net revenue on the sales of devices covered by the patent-pending technology and services related to the therapy or use of devices covered by the patent-pending technology. For the years ended December 31, 2019 and 2018, the Company recorded approximately $59 thousand and $0, respectively, in royalty expenses in its consolidated statement of operations.

(b) On October 30, 2017, HMI amended the Asset Purchase Agreement with A&B which specified that if the Company fails to obtain FDA marketing authorization for commercialization of or otherwise fails to ensure that the PoNS device is available for purchase by the U.S. Government by December 31, 2021, the Company would be subject to a $2.0 million contract penalty payable to A&B, unless the Company receives an exemption for the requirement of FDA marketing authorization from the U.S. Army Medical Material Agency. In December 2018, the U.S. Army notified the Company that they were amending the Agreement such that the satisfaction of the obligation of the contract was changed from FDA marketing authorization of the PoNS device to submitting of an application for marketing authorization of the PoNS device with the FDA. As the Company submitted its application for marketing authorization of the PoNS device to the FDA on August 31, 2018, and with copies of the submission documents provided to the U.S. Army, the Company has met its obligation under the amended agreement. Based on this amendment the Company has determined that the possibility of a payment under this contractual penalty is remote.

(c) In November 2014, the Company signed a development and distribution agreement with Altair LLC to apply for registration and distribution of the PoNS device in the territories of the former Soviet Union. Through March 31, 2019, the Company was entitled to receive a 7% royalty on sales of the devices within the territories. Altair terminated the distribution agreement effective May, 20, 2019. The Company made no commercial sales in the territories pursuant to the distribution agreement.

(d) In March 2017, the Company entered into a lease for office space in Newtown, Pennsylvania. The initial term of the lease is from July 1, 2017 through December 31, 2022, with an option to extend until 2027. In July 2017, the Company amended the contract to commence the lease on July 17, 2017 through January 16, 2023, with an option to extend until January 2028. It is not reasonably certain at this point in time that the

Company will elect to utilize the option to extend. Monthly rent plus utilities will be approximately $20 thousand per month beginning in January 2018 with a 3% annual increase.

The following table summarizes the Company's operating lease information including future minimum lease payments under a non-cancellable lease as of December 31, 2019 (amounts in thousands):

For the Year Ending December 31, 2019	
Operating lease cost	$ 224
Operating lease – operating cash flows	$ 246
Weighted average remaining lease term	3.05 years
Weighted average discount rate	15.1%
Future minimum lease payments under non-cancellable lease as of December 31, 2019 were as follows:	
For the Period Ending December 31,	
2020	$ 253
2021	260
2022	267
2023	10
Total future minimum lease payments	**790**
Less imputed interest	(153)
Total liability	**$ 637**
Reported as of December 31, 2019	
Current operating lease liability	172
Non-current operating lease liability	465
Total	**$ 637**

(e) On December 29, 2017, HMI (formerly known as NeuroHabilitation Corporation) entered into a Manufacturing and Supply Agreement ("MSA") with Key Tronic Corporation ("Key Tronic"), for the manufacture and supply of the Company's PoNS device based upon the Company's product specifications as set forth in the MSA. Per the agreement, the Company shall provide to Key Tronic a rolling forecast for the procurement of parts and material and within normal lead times based on estimated delivery dates for the manufacture of the PoNS device. The term of the agreement is for three years and the agreement will automatically renew for additional consecutive terms of one year, unless cancelled by either party upon 180-day written notice to the other party prior to the end of the then current term. As of December 31, 2019, the Company had a $0.1 million obligation to Key Tronic to complete the Company's forecast for the procurement of materials necessary for the delivery of PoNS devices.

(f) In September 2018, the Company entered into an exclusive strategic alliance agreement with HTC and Heuro to establish up to three founding clinics to treat patients and create a replicable model for future clinic expansion. Under the terms of the agreement, the parties developed a clinic system to facilitate the commercialization of the PoNS Treatment in Canada. Under the terms of the agreement, the parties contracted with the clinics and developed a model for the clinics to deliver clinical services, featuring the PoNS Treatment to manage neurological conditions. During the second quarter of 2019, the Company entered into the clinic expansion phase of this alliance with the addition of three new PoNS authorized clinics, bringing the total number of clinics authorized to treat patients with the PoNS device to five in Canada. The agreement also provided for HTC to pay the Company CAD$750 thousand in three annual payments of CAD$250 thousand beginning December 31, 2019, in consideration for the exclusivity right the Company granted to Heuro. The Company and HTC governed the agreement through a joint steering committee, and each funded up to 50% of Heuro's operating budget as agreed upon by a joint steering committee and shared in the net profits and losses of Heuro on a 50/50 basis. On October 30, 2019, the Company entered into a Share Purchase Agreement with HTC to purchase Heuro. The receivable was

considered part of the consideration for acquisition and was imbedded in the purchase price allocation. See Note 2 for details of the transaction. For the years ended December 31, 2019 and 2018, the Company recorded $0.1 million and $0.2 million, respectively, in expenses for its share of the estimated costs incurred by Heuro. Additionally, for the year ended December 31, 2018, the Company recorded $0.2 million of expenses incurred by the Company in performing services on behalf of Heuro. The aforementioned expenses were recorded as general and administrative expenses in the Company's consolidated statement of operations and comprehensive loss. During the year ended December 31, 2019, the Company recorded $0.1 million in cost of sales for services rendered in the Company's consolidated statement of operations and comprehensive loss. Further for the year ended December 31, 2019, the Company recognized $37 thousand in fee revenue related to its arrangement with HTC and Heuro (see Note 2).

8. VARIABLE INTEREST ENTITIES

A variable interest entity ("VIE") is an entity that either (i) has insufficient equity to permit the entity to finance its activities without additional subordinated financial support, or (ii) has equity investors who lack the characteristics of a controlling financial interest. Under ASC 810, an entity that holds a variable interest in a VIE and meets certain requirements would be considered to be the primary beneficiary of the VIE and is required to consolidate the VIE in its consolidated financial statements. In order to be considered the primary beneficiary of a VIE, an entity must hold a variable interest in the VIE and have both:

- the power to direct the activities that most significantly impact the economic performance of the VIE; and
- the right to receive benefits from, or the obligation to absorb losses of the VIE that could be potentially significant to the VIE.

The Company regularly assesses its relationships with contractual third party and other entities for potential VIE's. In making this assessment, the Company considers the potential that its contracts or other arrangements provide subordinated financial support, absorb losses or rights to residual returns of the entity and the ability to directly or indirectly make decisions about the entity's activities. If the Company determines that it is the primary beneficiary of a VIE, the Company consolidates the statements of operations and financial condition of the VIE into its consolidated financial statements.

Unconsolidated Variable Interest Entity

Prior to the acquisition of Heuro on October 30, 2019 (see Note 2), the Company utilized the consolidation guidance under ASC 810 to determine whether Heuro was a VIE, and if so, whether the Company was the primary beneficiary of Heuro (see Note 7(f)). Prior to the aforementioned acquisition, the Company had concluded that Heuro was a VIE based on the fact that the equity investment at risk in Heuro was not sufficient. The Company's variable interests in Heuro arose from a profit sharing arrangement with Heuro. In determining whether the Company was the primary beneficiary and whether the Company had the right to receive benefits and the obligation to absorb losses that could potentially be significant to the VIE, the Company evaluated its economic interest in Heuro.

This evaluation considered all relevant factors of Heuro's structure, including its capital structure, contractual rights to earnings (losses) as well as other contractual arrangements that had the potential to be economically significant. Following the guidance in ASC 810, although the Company had the obligation to absorb losses prior to October 30, 2019, the Company concluded that it was not the primary beneficiary, as it did not have the power to direct the activities that most significantly affected the economic performance of Heuro. The significant economic activities identified were financing activities, research and development activities, commercialization activities, supply and distribution activities, business strategy activities and clinic expansion activities. The evaluation of each of these factors in reaching a conclusion about the potential significance of the Company's economic interests and control was a matter that required the exercise of professional judgement.

Accordingly, prior to October 30, 2019, the Company did not consolidate Heuro in its consolidated financial statements nor did the Company have any carrying amounts for assets and liabilities relating to the variable interest in the VIE. Upon completion of the acquisition of Heuro on October 30, 2019, the Company consolidates Heuro's results in its consolidated financial statements.

9. RELATED PARTY TRANSACTIONS

For the years ended December 31, 2019 and 2018, the Company paid approximately $27 thousand and $33 thousand, respectively, in consulting fees to a director of the Company. As of December 31, 2019, the Company owed $5 thousand to a director for consulting services.

During April 2016, the Company entered into a consulting agreement with Montel Media, Inc. ("Montel Media"), pursuant to which Montel Media provides consulting services for the promotion of the Company's clinical trials and ongoing media and marketing strategies. Under the agreement, Montel Media received $15 thousand per month. During the first quarter of 2018, the Company terminated its agreement with Montel Media. Montel Media is owned by Montel Williams, who beneficially owns greater than 5% of the Company's common stock. The Company paid Montel Media $45 thousand for the year ended December 31, 2018 pursuant to the consulting agreement. The Company made no payments to Montel Media for the year ended December 31, 2019

For the year ended December 31, 2018, a benefit of $0.3 million, which included a foreign exchange gain of $18 thousand was included in the change in fair value of derivative financial instruments as the fair value of stock-based compensation attributed to the options granted to a director for consulting services rendered with respect to the design and development of the PoNS device. With the adoption of ASC 2018-07 during the third quarter of 2018, all non-employee stock-based compensation are no longer recorded as derivative financial instruments.

The Company's Chief Medical Officer was a founding member of Clinvue LLC ("Clinvue"), a company that provided regulatory advisory services to the Company until it ceased operations during the fourth quarter of 2018. The Company paid Clinvue approximately $0.1 million for consulting services in the year ended December 31, 2018. The Company made no payments to Clinvue for the year ended December 31, 2019.

10. SOLE-SOURCE COST-SHARING AGREEMENT AND COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

In July 2015, the Company entered into a sole source cost sharing agreement with the U.S. Army Medical Research and Materiel Command ("USAMRMC"). Under the terms of the contract, the USAMRMC reimbursed the Company up to $3.0 million to conduct a registrational trial investigating the safety and effectiveness of the PoNS device for the treatment of chronic balance deficits due to mmTBI. Reimbursement of expenses under the agreement was based on a schedule of milestones related to the completion of subjects in the trial. The original contract expired on December 31, 2016; however, the Company extended the agreement through December 31, 2017. On November 7, 2017, the Company received another extension of the contract agreement to December 31, 2018.

In addition, during the third quarter of 2017, the Company announced the execution of an extension to its Cooperative Research and Development Agreement with the USAMRMC through 2018 and extended the deadline for commercialization of the PoNS device to December 31, 2021.

In December 2018, the U.S. Army notified the Company that they were amending the U.S. Army Agreement such that the satisfaction of the obligation of the contract was changed from FDA marketing authorization of the PoNS device to submitting of an application for marketing authorization of the PoNS device with the FDA. The Company satisfied this obligation when it submitted its application for marketing authorization of the PoNS device to the FDA on August 31, 2018, and provided copies of the submission documents to the U.S. Army.

As of December 31, 2018, the Company had received a total of $3.0 million with respect to expenses reimbursed for amounts owed to the Company for completion of development milestones. All reimbursement amounts received are credited directly to the accounts in which the original expenses were recorded, including research and development, wages and salaries, and legal expenses.

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Balance Sheets
(Except for share data, amounts in thousands)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets		
Cash	$ 2,680	$ 5,459
Accounts receivable, net	80	210
Other receivables	138	364
Inventory, net	572	598
Prepaid expenses	666	610
Total current assets	4,136	7,241
Property and equipment, net	463	712
Other assets		
Goodwill	725	1,242
Intangible assets, net	579	582
Operating lease right-of-use asset, net	105	552
Other assets	18	18
Total other assets	1,427	2,394
TOTAL ASSETS	**$ 6,026**	**$ 10,347**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 720	$ 1,676
Accrued liabilities	1,399	1,519
Operating lease liability	107	172
Derivative financial instruments	—	5
Deferred revenue	339	430
Total current liabilities	2,565	3,802
Non-current liabilities		
Operating lease liability	47	465
Deferred revenue	217	245
TOTAL LIABILITIES	**2,829**	**4,512**
Commitments and contingencies (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Class A common stock, $0.001 par value; 150,000,000 shares authorized; 1,295,805 and 877,672 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	120,257	111,509
Accumulated other comprehensive loss	(693)	(902)
Accumulated deficit	(116,368)	(104,773)
TOTAL STOCKHOLDERS' EQUITY	**3,197**	**5,835**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 6,026**	**$ 10,347**

(The accompanying notes are an integral part of the condensed consolidated financial statements.)

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands except shares and per share data)

	Nine Months Ended September 30,	
	2020	2019
Revenue:		
Product sales, net	$ 441	$ 1,295
Fee revenue	9	49
License revenue	20	—
Total operating revenue	**470**	**1,344**
Cost of sales:		
Cost of product sales	187	538
Gross profit	**283**	**806**
Operating expenses:		
Research and development	3,755	6,462
Selling, general and administrative	7,625	12,715
Amortization expense	287	—
Total operating expenses	**11,667**	**19,177**
Operating loss	**(11,384)**	**(18,371)**
Other income (expense):		
Other income	63	35
Change in fair value of derivative financial instruments	4	14,033
Foreign exchange gain (loss)	(278)	(147)
Total other income (expense)	**(211)**	**13,921**
Net loss	**(11,595)**	**(4,450)**
Other comprehensive loss:		
Foreign currency translation adjustments	209	(168)
Comprehensive loss	**$ (11,386)**	**$ (4,618)**
Net loss per share		
Basic	**$ (10.36)**	**$ (6.02)**
Diluted	**$ (10.36)**	**$ (6.02)**
Weighted average shares outstanding		
Basic	**1,119,639**	**739,115**
Diluted	**1,119,639**	**739,115**

(The accompanying notes are an integral part of the condensed consolidated financial statements.)

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Nine Months Ended September 30, 2020 and 2019
(Except share and per share data, amounts in thousands)

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2018	**737,938**	**$ 1**	**$105,436**	**$ (591)**	**$ (94,992)**	**$ 9,854**
Proceeds from the exercise of stock options and warrants	2,134	—	215	—	—	215
Settlement of restricted stock units	27	—	—	—	—	—
Reclassification of derivative financial instruments from exercise of warrants	—	—	35	—	—	35
Stock-based compensation	—	—	3,336	—	—	3,336
Foreign currency translation adjustments	—	—	—	(168)	—	(168)
Net loss	—	—	—	—	(4,450)	(4,450)
Balance as of September 30, 2019	**740,099**	**$ 1**	**$109,022**	**$ (759)**	**$ (99,442)**	**$ 8,822**

	Common Stock, $0.001 par value		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2019	**877,672**	**$ 1**	**$ 111,509**	**$ (902)**	**$ (104,773)**	**$ 5,835**
Proceeds from the issuance of common stock from At-the-Market program	232,526	—	5,043	—	—	5,043
Proceeds from issuance of common stock from the March 2020 Offering	178,776	—	1,348	—	—	1,348
Warrant issuance from the March 2020 Offering	—	—	842	—	—	842
Share issuance costs	—	—	(506)	—	—	(506)
Settlement of restricted stock units	6,831	—	—	—	—	—
Stock-based compensation	—	—	2,021	—	—	2,021
Foreign currency translation adjustments	—	—	—	209	—	209
Net loss	—	—	—	—	(11,595)	(11,595)
Balance as of September 30, 2020	**1,295,805**	**$ 1**	**$120,257**	**$ (693)**	**$ (116,368)**	**$ 3,197**

(The accompanying notes are an integral part of the condensed consolidated financial statements.)

Helius Medical Technologies, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(Amounts in thousands)

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$(11,595)	$ (4,450)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative financial instruments	(4)	(14,033)
Stock-based compensation expense	2,021	3,336
Unrealized foreign exchange loss	245	211
Depreciation expense	92	89
Amortization expense	287	—
Provision for doubtful accounts	160	—
Intangible asset impairment	182	—
Loss from disposal of property and equipment	110	—
Gain on lease modification	(56)	—
Changes in operating assets and liabilities:		
Accounts receivable	(30)	(380)
Other receivables	226	(123)
Inventory	26	(897)
Prepaid expenses	(56)	285
Other current assets	—	264
Operating lease liability	20	(9)
Accounts payable	(956)	(678)
Accrued liabilities	(120)	(75)
Deferred revenue	(119)	—
Net cash used in operating activities	**(9,567)**	**(16,460)**
Cash flows from investing activities:		
Purchase of property and equipment	(14)	(260)
Proceeds from sale of property and equipment	61	—
Internally developed software	(7)	—
Net cash provided by (used in) investing activities	**40**	**(260)**
Cash flows from financing activities:		
Proceeds from the issuances of common stock and warrants	7,233	—
Share issuance costs	(506)	(52)
Proceeds from the exercise of stock options and warrants	—	215
Proceeds from Paycheck Protection Program Loan	323	—
Repayment of Paycheck Protection Program Loan	(323)	—
Net cash provided by financing activities	**6,727**	**163**
Effect of foreign exchange rate changes on cash	21	(7)
Net decrease in cash	(2,779)	(16,564)
Cash at beginning of period	5,459	25,583
Cash at end of period	**$ 2,680**	**$ 9,019**

(The accompanying notes are an integral part of the condensed consolidated financial statements.)

Helius Medical Technologies, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS

Helius Medical Technologies, Inc. ("we" or the "Company"), is a neurotech company focused on neurological wellness. The Company's purpose is to develop, license or acquire unique and non-invasive technologies targeted at reducing symptoms of neurological disease or trauma.

The Company's first product, known as the Portable Neuromodulation Stimulator ("PoNS™"), is authorized for sale in Canada as a class II, non-implantable medical device intended as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from multiple sclerosis ("MS",) and chronic balance deficit due to mild-to-moderate traumatic brain injury ("mmTBI") and is to be used in conjunction with physical therapy ("PoNS Treatment™"). It is an investigational medical device in the United States, the European Union ("EU"), and Australia ("AUS"). The device is currently under review for de novo classification and clearance by the U.S. Food and Drug Administration (the "FDA") as a potential treatment for gait deficit due to symptoms of MS. It is also under premarket review by the AUS Therapeutic Goods Administration. PoNS Treatment™ is not currently commercially available in the United States, the European Union or Australia.

The Company was incorporated in British Columbia, Canada on March 13, 2014. On May 28, 2014, we were reincorporated from British Columbia to the State of Wyoming, and on July 20, 2018, we were reincorporated from the State of Wyoming to the State of Delaware. We are headquartered in Newtown, Pennsylvania. On December 21, 2018, the Company's wholly owned subsidiary, NeuroHabilitation Corporation, changed its name to Helius Medical, Inc ("HMI"). On January 31, 2019, the Company formed another wholly owned subsidiary, Helius NeuroRehab, Inc., ("HNR"), a Delaware corporation. On October 10, 2019, the Company formed Helius Canada Acquisition Ltd. ("HCA"), a company incorporated under the federal laws of Canada and a wholly owned subsidiary of Helius Medical Technologies (Canada), Inc. ("HMC"), a company incorporated under the federal laws of Canada, which acquired Heuro Canada, Inc. ("Heuro") from Health Tech Connex Inc. ("HTC") on October 30, 2019.

2020 Reverse Stock Split

Effective after the close of business on December 31, 2020, the Company completed a 1-for-35 reverse stock split of its common stock ("2020 Reverse Stock Split"). The 2020 Reverse Stock Split did not change the par value of the Company's common stock or the number of common or preferred shares authorized by the Company's Certificate of Incorporation. All share and per-share amounts have been retrospectively adjusted to reflect the 2020 Reverse Stock Split for all periods presented.

Going Concern Uncertainty

As of September 30, 2020, the Company had cash of $2.7 million. For the nine months ended September 30, 2020, the Company had an operating loss of $11.4 million, and as of September 30, 2020, its accumulated deficit was $116.4 million. For the nine months ended September 30, 2020, the Company had $0.5 million of revenue from the commercial sale of products or services. The Company expects to continue to incur operating losses and net cash outflows until such time as it generates a level of revenue to support its cost structure. There is no assurance that the Company will achieve profitable operations, and, if achieved, whether it will be sustained on a continued basis. These factors indicate substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are filed. The Company's condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business; no adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

The Company intends to fund ongoing activities by utilizing its current cash on hand, cash received from the sale of its PoNS™ device in Canada and by raising additional capital through equity or debt financings. As discussed further in Note 8, on October 26, 2020, the Company closed a private placement and received net proceeds of approximately $3.2 million. There can be no assurance that the Company will be successful in raising that additional capital or that such capital, if available, will be on terms that are acceptable to the Company. If the Company is unable to raise sufficient additional capital, the Company may be compelled to reduce the scope of its operations and planned capital expenditures.

Risks and Uncertainties

COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout the United States and around the world. The Company's business, results of operations and financial condition have been and may continue to be adversely impacted by the COVID-19 pandemic and global economic conditions. The outbreak and spread of COVID-19 has significantly increased economic uncertainty. Authorities implemented numerous measures to try to contain COVID-19, such as travel bans and restrictions, quarantines, shelter in place orders, and business shutdowns. The COVID-19 pandemic initially led to the closure of PoNS Authorized clinic locations across Canada. While all clinics have re-opened, they are all currently operating at reduced capacity, and patients have been and may continue to be less willing to return to these clinics, impacting our commercial activities and our customer engagement efforts. In addition, the resurgence of COVID-19 cases across Canada in the fourth quarter of 2020 has led to further restrictions on clinic activities. Moreover, the Company's ability to conduct its ongoing clinical experience programs in Canada has been and may continue to be impaired due to trial participants' attendance being adversely affected by COVID-19, leading to further delays in the development and approval of the Company's product candidate. In addition, the COVID-19 pandemic has and may continue to cause delays in the Company's suppliers' ability to ship materials that the Company relies upon, and disruptions in business or governmental operations due to COVID-19 may delay the timing for the submission and approval of the Company's marketing applications with regulatory agencies. Further, the economic impact of the COVID-19 pandemic could affect the Company's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

The extent to which the COVID-19 pandemic will continue to impact the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. The Company does not know yet the full extent of the impact of COVID-19 on its business, operations or the global economy as a whole.

Nasdaq Delisting

On March 23, 2020, the Company received a letter (the "Notice") from the Listing Qualifications staff of Nasdaq indicating that, based on the closing bid price of the Company's Class A common stock (the "common stock") for the 30 consecutive business days preceding the Notice, the Company no longer meets the requirement to maintain a minimum bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Notice did not result in the immediate delisting of the Company's common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided a period of 180 calendar days in which to regain compliance.

On April 17, 2020, the Company received a second letter (the "Second Notice") for the Listing Qualifications staff of Nasdaq stating that the 180-day period to regain compliance with the Minimum Bid Price Requirement has been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq has stated that compliance periods were suspended from April 16, 2020 until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period to regain compliance with the Minimum Bid Price Requirement. As a result of this extension, the Company was given to until December 3, 2020 to regain compliance with the Minimum Bid Price Requirement.

On December 4, 2020, the Company received notice from the Listing Qualifications staff of Nasdaq indicating that the Company was not eligible for an additional 180 day extension to meet the Minimum Bid Price Requirement. As a result, the Staff determined that the Company's securities would be subject to delisting unless the Company timely requests a hearing before the Panel. The Company timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concludes and an extension granted by the Panel expires. An oral hearing has been scheduled for early 2021 (See Note 8).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The condensed consolidated financial statements have also been prepared on a basis substantially consistent with, and should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2019, included in its Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 12, 2020. The Company's reporting currency is the U.S. Dollar ("USD$").

Use of Estimates

The preparation of the condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and disclosure of contingent assets and liabilities. Significant estimates include the assumptions used in the fair value pricing model for stock-based compensation, derivative financial instruments and deferred income tax asset valuation allowance. Financial statements include estimates which, by their nature, are uncertain. Actual outcomes could differ from these estimates.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements reflect the operations of Helius Medical Technologies, Inc. and its wholly owned subsidiaries. The usual condition for a controlling financial interest is ownership of a majority of the voting interests of an entity. However, a controlling financial interest may also exist through arrangements that do not involve controlling voting interests. As such, the Company applies the guidance of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 810 – *Consolidation* ("ASC 810"), to determine when an entity that is insufficiently capitalized or not controlled through its voting interests, referred to as a variable interest entity should be consolidated. All intercompany balances and transactions have been eliminated.

Concentrations of Credit Risk

The Company is subject to credit risk with respect to its cash. Amounts invested in such instruments are limited by credit rating, maturity, industry group, investment type and issuer. The Company is not currently exposed to any significant concentrations of credit risk from these financial instruments. The Company seeks to maintain safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements and a competitive after-tax rate of return.

Receivables

Accounts receivables are stated at their net realizable value. In determining the appropriate allowance for doubtful accounts, the Company considers a combination of factors, such as the aging of trade receivables, its customers' financial strength, and payment history. Changes in these factors, among others, may lead to

adjustments in the Company's allowance for doubtful accounts. The calculation of the allowance required judgment by Company management. As of September 30, 2020, the Company's accounts receivable of $0.1 million, is net of an allowance for doubtful accounts of $0.4 million and is the result of revenue from product sales. As of December 31, 2019, the Company's accounts receivable of $0.2 million, is net of an allowance for doubtful accounts of $0.2 million and is the result of revenue from product sales.

Other receivables as of September 30, 2020 and December 31, 2019 included refunds from research and development ("R&D") tax credits of $21 thousand and $0.2 million, respectively, and Goods and Services Tax ("GST") and Quebec Sales Tax ("QST") refunds of $0.1 million and $0.1 million, respectively, related to the Company's Canadian expenditures.

Inventory

The Company's inventory consists of raw materials, work in progress and finished goods of the PoNS device. Inventory is stated at the lower of cost (average cost method) or net realizable value. Adjustments to reduce the cost of inventory to its net realizable value are made if required. The Company calculates provisions for excess inventory based on inventory on hand compared to anticipated sales or usage. Management uses its judgment to forecast sales or usage and to determine what constitutes a reasonable period. There can be no assurance that the amount ultimately realized for inventories will not be materially different than that assumed in the calculation of the reserves. Inventory markdowns to net realizable value of $2 thousand was recorded during the nine months ended September 30, 2020. No inventory markdowns to net realizable value were recorded during the nine months ended September 30, 2019.

As of September 30, 2020 and December 31, 2019, inventory consisted of the following (amounts in thousands):

	As of September 30, 2020	As of December 31, 2019
Raw materials	$ 159	$ 144
Work-in-process	446	375
Finished goods	19	129
Inventory	**$ 624**	**$ 648**
Inventory reserve	(52)	(50)
Total inventory, net of reserve	**$ 572**	**$ 598**

Property and Equipment

Property and equipment are carried at cost, less accumulated depreciation. Depreciation is recognized using the straight-line method over the useful lives of the related asset or the term of the related lease. Expenditures for maintenance and repairs, which do not improve or extend the expected useful life of the assets, are expensed to operations while major repairs are capitalized. The estimated useful life of the Company's leasehold improvements is over the shorter of its lease term or useful life of 5 years; the estimated useful life for the Company's furniture and fixtures is 7 years; and equipment has an estimated useful life of 15 years, while computer software and hardware has an estimated useful life of 3 to 5 years.

As of September 30, 2020 and December 31, 2019, property and equipment consisted of the following (amounts in thousands):

	As of September 30, 2020	As of December 31, 2019
Leasehold improvement	$ 64	$ 182
Furniture and fixtures	93	247
Equipment	300	286
Computer software and hardware	182	182
Property and equipment	**639**	**897**
Less accumulated depreciation	(176)	(185)
Property and equipment, net	**$ 463**	**$ 712**

Depreciation expense was $92 thousand and $89 thousand for the nine months ended September 30, 2020 and 2019, respectively.

During the nine months ended September 30, 2020, the Company sold furniture and fixtures with a net book value of $118 thousand for $61 thousand. Additionally, the Company abandoned leasehold improvements with a net book value of $53 thousand. The loss on the disposal of the furniture and fixtures and leasehold improvements of $110 thousand was recorded as selling, general and administrative expense in the condensed consolidated statements of operations and comprehensive loss.

Business Combinations

Transactions in which the Company obtains control of a business are accounted for according to the acquisition method as described in FASB ASC 805 – Business Combinations. The assets acquired and liabilities assumed are recognized and measured at their fair values as of the date control is obtained. Acquisition related costs in connection with a business combination are expensed as incurred. Contingent consideration is recognized and measured at fair value at the acquisition date and until paid re-measured on a recurring basis. It is classified as a liability based on appropriate GAAP.

On October 30, 2019, the Company and HTC entered into a Share Purchase Agreement (the “SPA”) whereby the Company, through its wholly owned subsidiary, acquired Heuro from HTC. Under the terms of the SPA, total consideration of approximately CAD$2.1 million (USD$1.6 million) was transferred to HTC, which included (1) cash of CAD$0.5 million (USD$0.4 million), (2) delivery of 55 PoNS devices for which the fair value was determined to be CAD$0.5 million (USD$0.4 million), (3) the forgiveness of CAD$750 thousand (USD$0.5 million) receivable from the September 2018 strategic alliance agreement and (4) the exclusivity rights granted to HTC in the Co-Promotion Agreement (as defined below) to provide PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia with a determined fair value of CAD$0.4 million (USD$0.3 million). The transaction has been accounted for as a business combination.

The acquisition related costs were $0.1 million and were accounted for as selling, general and administrative expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

The following table summarizes the recognized fair values of identifiable assets acquired and liabilities assumed as of October 30, 2019:

	October 30, 2019 Fair Value
Assets:	
Cash and cash equivalents	$ 1
Other receivables	19
Fixed assets	7
Intangibles	1,053
Goodwill	737
Total assets	**$ 1,817**
Liabilities:	
Accounts payable	$ 186
Other current liabilities	9
Total liabilities	**$ 195**
Net assets acquired	**$ 1,622**

The fair values assigned to identifiable intangible assets assumed were based on management's estimates and assumptions as of such date and are considered finalized. The Company recorded measurement adjustments of $0.4 million during the nine months ended September 30, 2020, all of which was recorded during the first quarter of 2020. The recorded adjustments related to the recognition of reacquired exclusivity rights.

Acquired intangibles consisted of customer relationships, proprietary technology and reacquired rights. The remaining useful life at acquisition was 1.25 years, 5 years and 3.87 years, respectively, and the acquired intangibles are amortized using the straight-line method.

Factors considered by the Company in determination of goodwill include synergies, strategic fit and other benefits that do not meet the recognition criteria of acquired identifiable intangible assets. The recognized goodwill of $0.7 million is not expected to be deductible for tax purposes.

The fair value of 55 PoNS devices which we agreed to transfer to HTC pursuant to the SPA in the amount of CAD$0.5 million will be recognized as revenue within the consolidated statements of operations and comprehensive loss once control has been transferred in accordance with ASC 606. As of December 31, 2019, the control had not been transferred resulting in the fair value being recorded as deferred revenue on the condensed consolidated balance sheet. As of September 30, 2020, the control of 11 devices had been transferred resulting in recognition of revenue for these devices. The fair value of the remaining 44 devices is still recorded as deferred revenue on the condensed consolidated balance sheet.

In connection with the SPA, on October 30, 2019, the Company entered into a Clinical Research and Co-Promotion Agreement with HTC (the "Co-Promotion Agreement"), whereby each company will promote the sales of the Company's PoNS Treatment and HTC's NeuroCatch™ device throughout Canada. This co-promotion arrangement terminates upon the earlier of the collection of data from 200 patients in Canada and December 31, 2020. Also, subject to certain terms and conditions, Helius granted to HTC the exclusive right to provide the PoNS Treatment in the Fraser Valley and Vancouver metro regions of British Columbia, where HTC has operated a PoNS authorized clinic since February 2019. HTC will purchase the PoNS devices for use in these regions exclusively from the Company and on terms no less favorable than the then-current standard terms and conditions. This exclusivity right has an initial term of ten (10) years, renewable by HTC for one additional ten (10) year term upon sixty (60) days' written notice to Helius. The Co-Promotion Agreement had a fair value of CAD$360 thousand at the time of acquisition. License revenue will be recognized in connection with the Co-Promotion Agreement ratably over the ten-year term.

Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair values underlying net assets acquired in an acquisition. All of the Company's goodwill as of September 30, 2020 is the result of the Heuro acquisition discussed above. Goodwill is not amortized, but rather will be tested annually for impairment or more frequently if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The Company will test goodwill for impairment annually in the fourth quarter of each year using data as of October 1 of that year.

Goodwill is allocated to and evaluated for impairment at the Company's one identified reporting unit. Goodwill is tested for impairment by either performing a qualitative evaluation or a quantitative test. The qualitative evaluation is an assessment of factors to determine whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. The Company may elect not to perform the qualitative assessment for its reporting unit and perform the quantitative impairment test. The quantitative goodwill impairment test requires the Company to compare the carrying value of the reporting unit's net assets to the estimated fair value of the reporting unit.

If the estimated fair value exceeds the carrying value, no further evaluation is required, and no impairment loss is recognized. If the carrying amount of a reporting unit, including goodwill, exceeds the estimated fair value, the excess of the carrying value over the estimated fair value is recorded as an impairment loss, the amount of which is not to exceed the total amount of goodwill allocated to the reporting unit.

The COVID-19 pandemic was a triggering event for testing whether goodwill is impaired. The Company performed quantitative assessments at March 31, 2020, June 30, 2020 and September 30, 2020. As a result of these assessments, the Company determined that the estimated fair value of the reporting unit exceeded the carrying value of the reporting unit. Therefore, the Company concluded that goodwill was not impaired as of any of the aforementioned periods. The Company will continue to monitor the impacts of the COVID-19 pandemic in future periods.

The following is a summary of the activity for the nine month period ended September 30, 2020 for goodwill:

Goodwill	2020
Carrying amount at beginning of period	$1,242
Business acquisition fair value allocation adjustment	(454)
Foreign currency translation	(63)
Carrying amount at end of period	$ 725

Definite-lived intangibles consist principally of acquired customer relationships, proprietary software and reacquired rights as well as internally developed software. All are amortized straight-line over their estimated useful lives. Amortization expense related to intangible assets was $0.3 million during the nine months ended September 30, 2020. No amortization expense related to intangible assets was recorded during the nine months ended September 30, 2019.

The Company reviews long-lived assets, including definite-lived intangible assets subject to amortization, for impairment whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Recoverability is assessed for the carrying value of assets held for use based on a review of undiscounted projected cash flows. Impairment losses, where identified, are measured as the excess of the carrying value of the long-lived asset over its estimated fair value as determined by discounted projected cash flows. During the nine months ended September 30, 2020, the Company incurred an intangible asset impairment loss of $0.2 million related to the customer relationships, all of which was incurred during the first quarter of 2020, which is included in selling, general and administrative expenses in the accompanying condensed consolidated statement of operations and comprehensive loss.

Intangible assets as of September 30, 2020 and December 31, 2019 consist of the following:

	Useful Life	As of September 30, 2020 Gross Carrying Amount	As of September 30, 2020 Accumulated Amortization	As of December 31, 2019 Gross Carrying Amount	As of December 31, 2019 Accumulated Amortization
Customer relationships	1.25 years	$ 227	$ (191)	$ 423	$ (55)
Acquired proprietary software	5 years	143	(26)	148	(5)
Reacquired rights	3.87 years	480	(113)	—	—
Internally developed software	3 years	82	(23)	75	(4)
Total intangible assets		$ 932	$ (353)	$ 646	$ (64)

Amortization expense is anticipated to be as follows in future years:

For the Year Ending December 31,	
2020 (remaining 3 months)	$ 73
2021	189
2022	176
2023	117
2024	24
	$579

Leases

On January 1, 2019, the Company adopted ASU No. 2016-02, *Leases*, using the modified retrospective method. The Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed the Company to carry forward the historical lease classification. Adoption of this standard resulted in the recording of an operating lease right-of-use ("ROU") asset and corresponding operating lease liabilities of $0.7 million on January 1, 2019.

The Company does not record an operating lease ROU asset and corresponding lease liability for leases with an initial term of twelve months or less and recognizes lease expense for these leases as incurred over the lease term. The Company had only one operating lease, which was for its headquarters office in Newtown, Pennsylvania upon the adoption date. As of September 30, 2020, the Company has not entered into any additional lease arrangements, but did modify the existing lease arrangement. Operating lease ROU assets and operating lease liabilities are recognized upon the adoption date based on the present value of lease payments over the lease term. The Company does not have a public credit rating and as such used a corporate yield with a "CCC" rating by S&P Capital IQ with a term commensurate with the term of its lease as its incremental borrowing rate in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term. The Company's lease arrangement does not have lease and non-lease components which are to be accounted for separately (see Note 6).

Foreign Currency

The Company's functional currency is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are translated into U.S. dollars using exchange rates in effect at the balance sheet date. Opening balances related to non-monetary assets and liabilities are based on prior period translated amounts, and non-monetary assets acquired, and non-monetary liabilities incurred are translated at the approximate exchange rate prevailing at the date of the transaction. Revenue and expense transactions are translated at the approximate exchange rate in effect at the time of the transaction. Foreign exchange gains and losses are included in the condensed consolidated statement of operations and comprehensive loss as foreign exchange (loss) gain.

The functional currency of HMC and HCA, the Company's Canadian subsidiaries, is the CAD$ and the functional currency of HMI and HNR is the USD$. Transactions in foreign currencies are recorded into the functional currency of the relevant subsidiary at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Revenues, expenses and cash flows are translated at the weighted-average rates of exchanges for the reporting period. The resulting currency translation adjustments are not included in the Company's condensed consolidated statements of operations and comprehensive loss for the reporting period, but rather are accumulated and gains and losses are recorded in foreign exchange (loss) gain, as a component of comprehensive loss, within the condensed consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for all stock-based payments and awards under the fair value-based method. The Company recognizes its stock-based compensation expense using the straight-line method. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

The Company accounts for the granting of stock options to employees and non-employees using the fair value method whereby all awards are measured at fair value on the date of the grant. The fair value of all employee-related stock options is expensed over the requisite service period with a corresponding increase to additional paid-in capital. Upon exercise of stock options, the consideration paid by the option holder, together with the amount previously recognized in additional paid-in capital is recorded as an increase to common stock, while the par value of the shares received is reclassified from additional paid in capital. Stock options granted to employees are accounted for as liabilities when they contain conditions or other features that are indexed to other than a market, performance or service condition.

In accordance with ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), stock-based payments to non-employees are measured based on the fair value of the equity instrument issued. Compensation expense for non-employee stock awards is recognized over the requisite service period following the measurement of the fair value on the grant date over the vesting period of the award.

The Company uses the Black-Scholes option pricing model to calculate the fair value of stock options. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. Changes in these assumptions can materially affect the fair value estimate.

Awards of options that provide for an exercise price that is not denominated in: (a) the currency of a market in which a substantial portion of the Company's equity securities trades, (b) the currency in which the employee's pay is denominated, or (c) the Company's functional currency, are required to be classified as liabilities.

Revenue Recognition

In accordance with the FASB's ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies the five-step model to contracts when it determines that it is probable it will collect substantially all of the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price, after consideration of variability and constraints, if any, that is allocated to the respective performance obligation when the performance obligation is satisfied.

Product Sales, net

During the first half of 2019, product sales were derived from the sale of the PoNS device and certain support services including services from the use of the NeuroCatch™ device, which is owned by HTC and assesses electroencephalogram brain waves related to cognition of patients participating in the PoNS Treatment at neuroplasticity clinics in Canada. The Company acted in an agency capacity for services performed using the NeuroCatch device and remitted CAD$600 for each patient assessed with the NeuroCatch device. According to the supply agreement with each of these clinics, the Company's performance obligation was met when it delivered the PoNS device to the clinic's facility and the clinic assumed title of the PoNS device upon acceptance. As such, revenue is recognized at a point in time. Shipping and handling costs associated with outbound freight before control of a product has been transferred to a customer is accounted for as a fulfillment cost and are included in cost of sales. Further, according to the Company's arrangement with HTC and Heuro, the Company shared 50/50 with Heuro in fees from support services excluding the CAD$600 payment for an assessment using the NeuroCatch device. For the nine months ended September 30, 2019, the Company recorded $1.3 million in product sales, net of $11 thousand for HTC's portion related to services performed using the NeuroCatch device. As described above, the Company modified its arrangement with HTC on October 30, 2019 and product sales were derived from the sale of the PoNS device alone as the NeuroCatch is sold directly to the neuroplasticity clinics in Canada by HTC. For the nine months ended September 30, 2020, the Company recorded $0.4 million in product sales. As of September 30, 2020, the control of 11 of the 55 PoNS devices included as consideration in the Heuro acquisition had been transferred resulting in revenue of $0.1 million being recognized which is included in the aforementioned $0.4 million in product sales for the nine months ended September 30, 2020. The fair value of the remaining 44 devices is recorded as deferred revenue of $0.3 million on the condensed consolidated balance sheet. The only returns during the nine months ended September 30, 2020 were the result of warranty returns for defective products. These returns were insignificant and any future replacements are expected to be insignificant.

Fee Revenue

During the nine months ended September 30, 2020, the Company recognized $9 thousand of fee revenue related to engaging new neuroplasticity clinics to provide the PoNS Treatment. During the nine months ended September 30, 2019, the Company recognized $49 thousand of fee revenue associated with the Company's agreement with HTC and Heuro that entitled the Company to 50% of the franchise fees collected by Heuro from each executed franchise agreement. As of September 30, 2020 and December 31, 2019, the Company had no contract assets or liabilities on its condensed consolidated balance sheets related to the supply agreements with each clinic.

License Revenue

The Company did not record any license revenue during the nine months ended September 30, 2019. As described above, the Company modified its arrangement with HTC on October 30, 2019. License revenue will be

recognized ratably over the ten-year term as the performance obligation is met in connection with the Co-Promotion Agreement. During the nine months ended September 30, 2020, the Company recognized revenues of $20 thousand in license fees associated with the Co-Promotion Agreement. Revenue not yet recognized of $0.2 million is recorded as deferred revenue on the condensed consolidated balance sheet.

Cost of Sales

Cost of product sales includes the cost to manufacture the PoNS device, royalty expenses, freight charges, customs duties, wages and salaries of employees involved in the management of the supply chain and logistics of fulfilling the Company's sales orders and certain support services provided by Heuro on the Company's behalf.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The asset and liability method provide that deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company records a valuation allowance to reduce deferred tax assets to the amount that is believed more likely than not to be realized.

The Company has adopted the provisions of ASC 740 *Income Taxes* regarding accounting for uncertainty in income taxes. The Company initially recognizes tax positions in the condensed consolidated financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of the tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts. Application requires numerous estimates based on available information. The Company considers many factors when evaluating and estimating its tax positions and tax benefits. These periodic adjustments may have a material impact on the condensed consolidated statements of operations and comprehensive loss. When applicable, the Company classifies penalties and interest associated with uncertain tax positions as a component of income tax expense in its condensed consolidated statements of operations and comprehensive loss.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. We continue to examine the impact that the CARES Act may have on our business. Currently, we do not believe the CARES Act will have a material impact on our accounting for income taxes.

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, development and manufacturing of clinical trial devices and devices for manufacturing testing and materials and supplies as well as regulatory costs related to post market surveillance, quality assurance complaint handling and adverse event reporting. R&D costs are charged to operations when they are incurred.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to

allocate resources and in assessing performance. The Company operates and manages its business within one operating and reportable segment. Accordingly, the Company reports the accompanying condensed consolidated financial statements in the aggregate in one reportable segment.

Derivative Financial Instruments

The Company evaluates its financial instruments and other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815, *Derivatives and Hedging* ("ASC 815"). The result of this accounting treatment is that the fair value of the derivative is re-measured at each balance sheet date and recorded as a liability or asset and the change in fair value is recorded in the condensed consolidated statements of operations and comprehensive loss. As of September 30, 2020 and December 31, 2019, the Company's derivative financial instruments accounted for in accordance with ASC 815 were comprised of warrants issued in connection with both public and/or private securities offerings. Upon settlement of a derivative financial instrument, the instrument is re-measured at the settlement date and the fair value of the underlying instrument is reclassified to equity.

The classification of derivative financial instruments, including whether such instruments should be recorded as liabilities/assets or as equity, is reassessed at the end of each reporting period. Derivative financial instruments that become subject to reclassification are reclassified at the fair value of the instrument on the reclassification date. Derivative financial instruments will be classified in the condensed consolidated balance sheet as current if the right to exercise or settle the derivative financial instrument lies with the holder.

Fair Value Measurements

The Company accounts for financial instruments in accordance with ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"). ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The Company's financial instruments recorded in its condensed consolidated balance sheets consist primarily of cash, accounts receivable, other current receivables, operating lease ROU asset, accounts payable, accrued liabilities, operating lease liability and derivative financial instruments. The book values of these instruments, with the exception of derivative financial instruments, non-current lease liability, operating lease ROU asset and non-current receivables approximate their fair values due to the immediate or short-term nature of these instruments.

The Company's derivative financial instruments are classified as Level 3 within the fair value hierarchy. Unobservable inputs used in the valuation of these financial instruments include volatility of the underlying share price and the expected term. See Note 3 for the inputs used in the Black-Scholes option pricing model as of September 30, 2020 and December 31, 2019 and the roll forward of the Company's derivative financial instruments. The Company's derivative financial instruments are comprised of warrants which are classified as liabilities.

The following table summarizes the Company's recurring fair value measurements for derivative financial instruments and stock-based compensation liability within the fair value hierarchy as of September 30, 2020 and December 31, 2019 (amounts in thousands):

	Fair Value	Level 1	Level 2	Level 3
September 30, 2020				
Liabilities:				
Derivative financial instruments	$ —	$ —	$ —	$ —
December 31, 2019				
Liabilities:				
Derivative financial instruments	$ 5	$ —	$ —	$ 5

There were no transfers between any levels for any of the periods presented.

In addition to assets and liabilities that are recorded at fair value on a recurring basis, the Company's assets and liabilities are also subject to nonrecurring fair value measurements. Generally, assets are recorded at fair value on a nonrecurring basis as a result of impairment charges. Due to the COVID-19 pandemic and the related risks and uncertainties, the Company's customer relationship intangible asset incurred an impairment loss during the nine months ended September 30, 2020 of $0.2 million, all of which was recorded during the first quarter of 2020, and has a remaining net book value of $36 thousand as of September 30, 2020. The fair value of this intangible asset was determined based on Level 3 measurements within the fair value hierarchy. Inputs to these fair value measurements included estimates of the amount and timing of the asset's net future discounted cash flows based on historical data, current trends and market conditions.

Basic and Diluted Loss per Share

Earnings or loss per share ("EPS") is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted EPS is computed by dividing net income (loss) by the weighted average of all potentially dilutive shares of common stock that were outstanding during the periods presented.

The treasury stock method is used in calculating diluted EPS for potentially dilutive stock options and share purchase warrants, which assumes that any proceeds received from the exercise of in-the-money stock options and share purchase warrants, would be used to purchase common shares at the average market price for the period, unless including the effects of these potentially dilutive securities would be anti-dilutive.

The basic and diluted loss per share for the periods noted below is as follows (amounts in thousands except shares and per share data):

	Nine Months Ended September 30,	
	2020	2019
Basic		
Numerator:		
Net loss	$ (11,595)	$ (4,450)
Denominator:		
Weighted average common shares outstanding	1,119,639	739,115
Basic net loss per share	**$ (10.36)**	**$ (6.02)**
Diluted		
Numerator:		
Net loss, basic	$ (11,595)	$ (4,450)
Effect of dilutive securities	—	—
Net loss, diluted	$ (11,595)	$ (4,450)
Denominator:		
Weighted average common shares outstanding – basic	1,119,639	739,115
Potential common share issuances:		
Incremental dilutive shares from equity instruments (treasury stock method)	—	—
Weighted average common shares outstanding	1,119,639	739,115
Diluted net loss per share	**$ (10.36)**	**$ (6.02)**

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the periods noted below, as they would have been anti-dilutive due to the Company's losses for the nine months ended September 30, 2020 and 2019 and because the exercise price of certain of these outstanding securities was greater than the average closing price of the Company's common stock.

	Nine Months Ended September 30,	
	2020	2019
Stock options outstanding	112,224	103,693
RSUs	164	—
Warrants outstanding	265,583	86,960
Total	**337,971**	**190,653**

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held and requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which amends the effective date of ASU 2016-13. Public business entities that meeting the definition of an SEC filer, excluding entities eligible to be a Smaller Reporting Company ("SRC") as defined by the SEC, are required to

adopt the standard for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are required to adopt the standard for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company meets the definition of an SRC and therefore the standard will not be effective until the beginning of 2023. The Company is evaluating the effect that ASU 2016-13 will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. The Company adopted this standard as of January 1, 2020 and the adoption did not have a material impact on the Company's condensed consolidated financial statements.

In November 2018, FASB issued ASU 2018-18, C*ollaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606,* which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company adopted this standard on January 1, 2020 and the adoption did not have a material impact on the Company's condensed consolidated financial statements.

3. COMMON STOCK AND WARRANTS

The Company's authorized capital stock pursuant to its Delaware charter consists of 150,000,000 authorized shares of common stock, at a par value per share of $0.001 and 10,000,000 authorized shares of preferred stock at a par value per share of $0.001. Holders of common stock are entitled to vote at any meeting of the Company's stockholders on the basis of one vote per share of common stock owned as of the record date of such meeting. Each share of common stock entitles the holder to receive dividends, if any, as declared by the Company's Board of Directors.

No dividends have been declared since inception of the Company through September 30, 2020. In the event of a liquidation, dissolution or winding-up of the Company, other distribution of assets of the Company among its stockholders for the purposes of winding-up its affairs or upon a reduction of capital, the stockholders shall, share equally, share for share, in the remaining assets and property of the Company.

On April 13, 2018, the Company issued 61,197 shares of its common stock and warrants to purchase 61,197 shares of the Company's common stock in an underwritten public offering at a price of $261.45 per share and accompanying warrant. On April 24, 2018, the Company closed on the sale of an additional 9,179 shares of its common stock and warrants to purchase 9,179 shares of the Company's common stock pursuant to the exercise of the underwriters' over-allotment option (collectively the "April 2018 Offering"). The Company received net proceeds of $16.3 million from the April 2018 Offering. The fair value of these warrants at issuance was approximately $7.4 million.

Each warrant issued in connection with the April 2018 Offering entitles the holder to acquire one additional share of common stock at an exercise price of CAD$428.75 per share on or before April 10, 2021. Pursuant to the guidance of ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the April 2018 Offering should be accounted for as liabilities as the ability to maintain an effective registration is outside of the Company's control and that it may be required to settle the exercise of the warrants in cash and because, as a result of the change in the Company's functional currency (see Note 2), the exercise prices of these warrants are in a currency other than the Company's functional currency. Consequently, the Company determined the fair value of each warrant issuance using the Black-Scholes option pricing model, with the remainder of the proceeds allocated to the common shares. As of September 30, 2020, 2,025 warrants had been exercised, all during 2018, for gross proceeds of CAD$0.9 million.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants issued in the April 2018 Offering using the Black-Scholes option pricing model as of the date of the initial closing of the offering and the date of the closing of the over-allotment option and September 30, 2020.

	September 30, 2020	April 24, 2018	April 13, 2018
Stock price	CAD$ 18.55	CAD$ 376.60	CAD$ 344.75
Exercise price	CAD$ 428.75	CAD$ 428.75	CAD$ 428.75
Warrant term	0.53 years	3.00 years	3.00 years
Expected volatility	107.16%	64.49%	64.20%
Risk-free interest rate	0.16%	2.02%	1.99%
Dividend rate	0.00%	0.00%	0.00%

On November 22, 2019, the Company issued 137,751 shares of its common stock in an underwritten public offering at a price of $12.25 per share. The Company received net proceeds of $1.1 million.

On January 27, 2020, the Company filed a Form S-3 shelf registration under the Securities Act which was declared effective by the SEC on February 6, 2020 (the "2020 Shelf"). In conjunction with the 2020 Shelf, on January 27, 2020, the Company entered into an At The Market Offering Agreement (the "2020 ATM") with H.C. Wainwright & Co., LLC ("Wainwright") under which the Company may offer and sell, from time to time at its sole discretion, to or through Wainwright, acting as agent and/or principal, shares of its common stock having an aggregate offering price of up to $11.34 million, which, in March 2020, was subsequently reduced to $9.15 million, including the shares previously sold under the 2020 ATM. For the nine months ended September 30, 2020, under the 2020 ATM, the Company sold and issued 232,526 shares of its common stock with an aggregated market value of $5.0 million at an average price of $21.68 per share and paid Wainwright a sales commission of approximately $181 thousand related to those shares.

On March 20, 2020, the Company, in a registered direct offering, issued an aggregate of 178,776 shares of its common stock at a price of $12.25 per share. Additionally, the Company issued unregistered warrants in a concurrent private placement to purchase up to 178,776 shares of its common stock at an exercise price of $16.10 per share. Gross proceeds from the offering (the "March 2020 Offering") were approximately $2.2 million. The underwriting discounts and commissions and offering expenses of $0.3 million were recorded to share issuance costs.

Each warrant issued in connection with the March 2020 Offering entitles the holder to acquire one additional share of common stock at an exercise price of $16.10 per share, which became exercisable on September 20, 2020 and will expire on March 20, 2025. Pursuant to the guidance of ASC 480 *Distinguishing Liabilities from Equity* and ASC 815 *Derivatives and Hedging*, the Company has determined that warrants issued in connection with the March 2020 Offering should be classified as equity as the warrants can be settled with unregistered shares. The relative fair value of these warrants at issuance was approximately $0.8 million and was included in additional paid-in capital.

The following table summarizes the weighted average assumptions used in estimating the fair value of the warrants granted in the March 2020 Offering using the Black-Scholes option pricing model as of the date of the closing of the offering on March 20, 2020.

	March 20, 2020
Stock price	$ 12.25
Exercise price	$ 16.10
Warrant term	5.50 years
Expected volatility	82.41%
Risk-free interest rate	0.52%
Dividend rate	0.00%

The following table summarizes warrants accounted for as liabilities and recorded as derivative financial instruments on the Company's condensed consolidated balance sheets for the nine months ended September 30, 2020 and 2019 (amounts in thousands):

	Nine Months Ended September 30,	
	2020	2019
Fair value of warrants at beginning of period	**$ 5**	**$ 13,769**
Exercise of warrants	—	(35)
Foreign exchange losses	(1)	382
Change in fair value of warrants during the period	(4)	(14,033)
Fair value of warrants at end of period	**$ —**	**$ 83**

These warrants which are classified as derivative financial instruments in the Company's condensed consolidated balance sheets are required to be re-measured at each reporting period, with the change in fair value recorded as a gain or loss in the change in fair value of derivative financial instruments, included in other income (expense) in the Company's condensed consolidated statements of operations and comprehensive loss. The fair value of the warrants will continue to be classified as a liability until such time as they are exercised, expire or there is an amendment to the respective agreements that renders these financial instruments to be no longer classified as such.

The fair value of all warrants classified as derivative financial instruments outstanding as of September 30, 2020 and December 31, 2019 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	September 30, 2020	December 31, 2019
Stock price	CAD$ 18.55	CAD$ 43.05
Exercise price	CAD$ 428.75	CAD$ 428.75
Warrant term	0.53 years	1.28 years
Expected volatility	107.16%	72.43%
Risk-free interest rate	0.16%	1.72%
Dividend rate	0.00%	0.00%

The following is a summary of the Company's warrant activity during the nine months ended September 30, 2020:

	Number of Warrants		Weighted Average Exercise Price	
	CAD	US	CAD$	USD$
Outstanding as of December 31, 2019	**68,351**	**18,607**	**$ 428.75**	**$ 428.40**
Granted	—	178,776	—	16.10
Cancelled/Expired	—	(151)	—	376.25
Exercised	—	—	—	—
Outstanding as of September 30, 2020	**68,351**	**197,232**	**$ 428.75**	**$ 54.71**

The Company's warrants outstanding and exercisable as of September 30, 2020 were as follows:

Number of Warrants Outstanding	Exercise Price	Expiration Date
7,740	USD$428.75	December 22, 2020
4,886	USD$428.75	December 28, 2020
5,830	USD$428.75	December 29, 2020
68,351	CAD$428.75	April 10, 2021
178,776	USD$16.10	March 20, 2025
265,583		

4. STOCK-BASED PAYMENTS

On May 15, 2018, the Company's Board of Directors authorized and approved the adoption of the 2018 Omnibus Incentive Plan, (as amended, the "2018 Plan"), which was effective upon approval by the stockholders of the Company on June 28, 2018 and under which an aggregate of 153,031 shares may be issued. This share reserve is the sum of 85,714 new shares, plus the 67,317 shares that remained available for issuance under the Company's 2016 Omnibus Incentive Plan (the "2016 Plan"), the predecessor incentive plan at the time of the adoption of the 2018 Plan. Pursuant to the terms of the 2018 Plan, the Company is authorized to grant stock options, as well as awards of stock appreciation rights, restricted stock, unrestricted shares, restricted stock units ("RSUs"), stock equivalent units and performance-based cash awards. These awards may be granted to directors, officers, employees and eligible consultants. Vesting and the term of an option is determined at the discretion of the Company's Board of Directors. Subsequent to the adoption of the 2018 Plan, the Company ceased granting awards under the 2016 Plan, the predecessor incentive plan. However, outstanding stock options granted prior to the effective date of the 2018 Plan are still governed by the 2016 Plan or the Company's 2014 Stock Incentive Plan, which preceded the 2016 Plan.

As of September 30, 2020, there was an aggregate of 96,798 shares of common stock remaining available for grant under the Company's 2018 Plan.

For the nine months ended September 30, 2020, the Company issued 23,112 stock options to employees and directors. The Company issued no stock options to consultants during the nine months ended September 30, 2020.

The following is a summary of the Company's stock option activity during the nine months ended September 30, 2020:

	Number of Stock Options	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	**99,018**	**$ 236.63**	**$ —**
Granted	23,112	16.42	—
Forfeited/Cancelled	(9,906)	(198.03)	—
Exercised	—	—	—
Outstanding as of September 30, 2020	**112,224**	**$ 194.68**	**$ —**
Exercisable as of September 30, 2020	**69,995**	**$ 149.62**	**$ —**

As of September 30, 2020, the unrecognized compensation cost related to non-vested stock options outstanding for employees and directors, was $4.1 million which will be recognized over a weighted-average remaining vesting period of approximately 2.8 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

The weighted average grant date fair value of employee and director stock options granted for the nine months ended September 30, 2020 was $10.50 per option and the grant date fair values of these stock options were estimated using the Black-Scholes option pricing model using the following weighted average assumptions:

	Nine Months Ended September 30, 2020
Stock price	$ 16.42
Exercise price	$ 16.42
Expected term	5.26 years
Expected volatility	77.35%
Risk-free interest rate	0.58%
Dividend rate	0.00%

As of September 30, 2020, the unrecognized compensation cost related to non-vested stock options outstanding for non-employees was $15 thousand which will be recognized over a weighted-average remaining vesting period of approximately 0.9 years. Compensation cost is not adjusted for estimated forfeitures, but instead is adjusted upon an actual forfeiture of a stock option.

Restricted Stock Awards

Beginning in the fourth quarter of 2019, certain members of the Company's executive management team elected to receive restricted stock awards in lieu of cash compensation under the 2018 Plan that vest upon issuance. The fair value of the restricted stock awards is based on the closing price of the Company's common stock on the day of the grant.

The following is a summary of the Company's restricted stock award activity for the nine months ended September 30, 2020:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding as of December 31, 2019	788	USD$21.17
Granted	6,207	17.62
Settled	(6,831)	18.13
Outstanding as of September 30, 2020	164	$13.54

Stock-Based Compensation Expense

Stock-based compensation expense is classified in the Company's condensed consolidated statements of operations and comprehensive loss as follows (amounts in thousands):

	Nine Months Ended September 30,	
	2020	2019
Research and development	$ 727	$ 643
Cost of sales	(1)	—
Selling, general and administrative	1,295	2,693
Total	**$2,021**	**$3,336**

Stock-based compensation expense for the nine months ended September 30, 2020 includes the reversal of $125 thousand of expense as a result of forfeitures due to the departure of our former chief executive officer in August 2020.

5. ACCRUED EXPENSES

Accrued expenses consisted of the following (amounts in thousands):

	As of	
	September 30, 2020	December 31, 2019
Employees benefits	$ 557	$ 722
Professional services	6	67
Legal fees	163	81
Royalty fees	5	13
Franchise fees	40	28
Severance	550	606
Other	78	2
Total	**$ 1,399**	**$ 1,519**

Accrued severance expenses as of September 30, 2020 included $0.5 million in severance costs related to the departure of our former chief executive officer in August 2020.

6. COMMITMENTS AND CONTINGENCIES

(a) On January 22, 2013, the Company entered into a license agreement with Advanced NeuroRehabilitation, LLC (“ANR”) for an exclusive right to ANR’s patent pending technology, claims and knowhow. In addition to the issuance of 91,628 shares of common stock to ANR, the Company agreed to pay a 4% royalty on net revenue on the sales of devices covered by the patent-pending technology and services related to the therapy or use of devices covered by the patent-pending technology. For the nine months ended September 30, 2020, the Company recorded approximately $15 thousand in royalty expenses in its condensed consolidated statement of operations and comprehensive loss. For the nine months ended September 30, 2019, the Company recorded approximately $52 thousand in royalty expenses in its condensed consolidated statement of operations and comprehensive loss.

(b) On October 30, 2017, HMI amended the Asset Purchase Agreement with A&B (HK) Company Ltd. (“A&B”) which specified that if the Company fails to obtain FDA marketing authorization for commercialization of or otherwise fails to ensure that the PoNS device is available for purchase by the U.S. Government by December 31, 2021, the Company would be subject to a $2.0 million contract penalty payable to A&B, unless the Company receives an exemption for the requirement of FDA marketing authorization from the U.S. Army Medical Material Agency. In December 2018, the U.S. Army notified the Company that it was amending the Agreement such that the satisfaction of the obligation of the contract was changed from FDA marketing authorization of the PoNS device to submitting of an application for marketing authorization of the PoNS device with the FDA. As the Company submitted its application for marketing authorization of the PoNS device to the FDA on August 31, 2018, and with copies of the submission documents provided to the U.S. Army, the Company has met its obligation under the amended agreement. Based on this amendment the Company has determined that the possibility of a payment under this contractual penalty is remote.

(c) In March 2017, the Company entered into a lease for office space in Newtown, Pennsylvania. The initial term of the lease was from July 1, 2017 through December 31, 2022, with an option to extend until 2027. In July 2017, the Company amended the contract to commence the lease on July 17, 2017 through January 16, 2023, with an option to extend until January 2028. Lease extension options were not included in the lease term as it was not reasonably certain that the Company would elect to utilize the option to extend. Monthly rent plus utilities were approximately $20 thousand per month beginning in January 2018 with a 3% annual increase.

In May 2020, the Company terminated its lease and entered into a new lease (the "Lease Amendment") for a smaller footprint of the current office space in Newtown, Pennsylvania. Lease payments under the original contract will be made through December 2020. The Lease Amendment was determined to be a partial termination that qualified as a change of accounting of the existing lease and not a separate contract. As such, the ROU assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification. The carrying value of the ROU asset decreased on a basis proportionate to the partial termination by approximately $0.4 million and the related lease liability decreased by approximately $0.4 million. The Company recorded a gain of approximately $0.1 million resulting from the difference between the reduction in the lease liability and the proportionate reduction of the ROU asset. This amount is recorded as a component of other income in the condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2020.

The initial lease term of the Lease Amendment is from July 1, 2020 through June 30, 2021, with options to extend for successive six month periods. Two lease extension options were included in the lease term as it was reasonably certain that the Company would elect to utilize the option to extend for this period of time. Monthly rent plus utilities will be approximately $5 thousand per month beginning in January 2021 with a 3% annual increase.

The following table summarizes the Company's operating lease information including future minimum lease payments under a non-cancellable lease as of September 30, 2020 (amounts in thousands).

For the Nine Months Ended September 30, 2020	
Operating lease cost	$ 57
Operating lease – operating cash flows	$ 189
Weighted average remaining lease term	1.75 years
Weighted average discount rate	7.2%
Future minimum lease payments under non-cancellable lease as of September 30, 2020 were as follows:	
For the Period Ending December 31,	
2020 (remaining three months)	$ 63
2021	63
2022	32
Total future minimum lease payments	**158**
Less imputed interest	(4)
Total liability	**$ 154**
Reported as of September 30, 2020	
Current operating lease liability	107
Non-current operating lease liability	47
Total	**$ 154**

(d) On December 29, 2017, HMI (formerly known as NeuroHabilitation Corporation) entered into a Manufacturing and Supply Agreement ("MSA") with Key Tronic Corporation ("Key Tronic"), for the manufacture and supply of the Company's PoNS device based upon the Company's product specifications as set forth in the MSA. Per the agreement, the Company shall provide to Key Tronic a rolling forecast for the procurement of parts and material and within normal lead times based on estimated delivery dates for the manufacture of the PoNS device. The term of the agreement is for three years and will automatically renew for additional consecutive terms of one year, unless cancelled by either party upon 180-day written notice to the other party prior to the end of the then current term. On June 1, 2020, HMI extended the existing manufacturing agreement with Key Tronic for a second three year term from December 29, 2020 until December 31, 2023. As of September 30, 2020, the Company did not have any outstanding

commitments to Key Tronic to complete the Company's forecasts for the procurement of materials necessary for the delivery of PoNS devices.

(e) The Company was granted a $323 thousand loan on April 13, 2020 under the Paycheck Protection Program (the "PPP Loan") established under the CARES Act. The Company planned to use the proceeds from the PPP Loan for covered payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act. However, based upon subsequent guidance issued by the Federal Government, including a presumption that publicly traded companies may not be eligible for a PPP loan, the Company returned the PPP Loan proceeds in May 2020 and paid interest for the period of time the loan was outstanding.

Legal Contingencies

Caramahai v. Helius Medical Technologies, Inc. et al.

On or about July 9, 2019, a putative shareholder class action lawsuit, *Caramahai v. Helius Medical Technologies, Inc. et al.*, Case No. 1:19-cv-06365 (S.D.N.Y.), was filed against the Company and three of its individual officers in the Southern District of New York ("the *Caramahai* Action"). The lawsuit alleges that the Company made materially false and misleading statements regarding the prospects for FDA approval of Helius' application for de novo classification and clearance of its PoNS device in the United States. As a result of these alleged misstatements, the *Caramahai* Action asserts claims on behalf of shareholders who bought or sold Helius common stock between from November 9, 2017 to April 10, 2019 for alleged violations of the federal securities laws, specifically Section 10(b) and Rule 10b-5 of the Securities Exchange Act of 1934, as amended.

On or about July 31, 2019, a putative shareholder class action lawsuit, *Evans v. Helius Medical Technologies, Inc. et al.*, Case No. 1:19-cv-07171 (S.D.N.Y.), was filed against the Company and three of its individual officers in the Southern District of New York (the "*Evans* Action"). The *Evans* Action alleges similar claims as the *Caramahai* Action.

On September 9, 2019, three Helius shareholders each filed motions in the *Caramahai* and *Evans* cases seeking to consolidate the two proceedings into a single putative class action. The individual motions also sought to have the movant appointed as Lead Plaintiff (the plaintiff responsible for prosecuting the class's claims and has the power to settle and release claims of all class members) and have the movant's attorneys appointed as Lead Counsel. On September 13 and 17, 2019, respectively, two of the movants filed notices withdrawing their motions on the ground that they did not appear to have "the largest financial interest in the relief sought by the class." The third movant was appointed Lead Plaintiff on April 28, 2020 and movant's attorneys were appointed as Lead Counsel.

During the second quarter of 2020, the plaintiffs voluntarily dismissed the lawsuit without prejudice, ending the case. The U.S. District Judge signed the final order dismissing the litigation on July 1, 2020.

7. RELATED PARTY TRANSACTIONS

During the nine months ended September 30, 2020, the Company paid approximately $5 thousand in consulting fees to a director of the Company. During the nine months ended September 30, 2019, the Company paid approximately $25 thousand in consulting fees to a director of the Company. As of September 30, 2020, the Company did not have an accrued liability for consulting fees to a director of the Company.

8. SUBSEQUENT EVENTS

On October 26, 2020, the Company closed on a private placement of an aggregate of 187,646 shares of common stock and warrants to purchase an aggregate of 93,817 shares of common stock at a purchase price of $18.20 per unit, consisting of one share and a warrant to purchase 0.50 shares of common stock, resulting in gross

proceeds of approximately $3.4 million, excluding the proceeds, if any, that the Company may receive in the future from the exercise of the warrants. The Company incurred $0.2 million in share issuance costs, including placement agent fees. The warrants have an initial exercise price of $15.82 per share and are exercisable for a period of three years from the date of issuance. The Company also issued warrants to the placement agent to purchase 961 shares of common stock, with an exercise price of $19.775 per share. An officer of the Company and affiliates of an officer and director of the Company participated in the private placement on the same terms and conditions as all other purchasers, except that they paid $18.354 per unit and their warrants have an exercise price of $16.1665 per share.

Pursuant to the securities purchase agreement for the private placement, if the Company issues any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination thereof, with certain exceptions, within twelve months of the closing of the private placement, each purchaser who subscribed for at least $250,000 has the right to participate in up to such purchaser's pro rata portion of 30% of the such subsequent financing on the same terms, conditions and price provided for in the subsequent financing.

The following table sets forth the Company's total stockholders' equity as reported as of September 30, 2020 and as adjusted on a pro forma basis to reflect the recently completed private placement (amounts in thousands):

Total stockholders' equity as of September 30, 2020	$3,197
Net proceeds from October 2020 private placement	3,244
Pro forma total stockholders' equity as of September 30, 2020	**$6,441**

Nasdaq Delisting

On December 4, 2020, the Company received notice from the Listing Qualifications staff of Nasdaq indicating that the Company was not eligible for an additional 180 day extension to meet the Minimum Bid Price Requirement. As a result, the Staff determined that the Company's securities would be subject to delisting unless the Company timely requests a hearing before the Panel. The Company timely submitted a request for a hearing before the Panel, which request stayed any suspension or delisting action by Nasdaq at least until the hearing process concludes and any extension granted by the Panel expires. On January 15, 2021, the Company received notice from the Staff that the bid price deficiency of the Company had been cured, and that the Company was in compliance with all applicable listing standards, and so the scheduled hearing before the Panel was cancelled.

647,772 Units consisting of shares of Class A common stock and warrants (and shares of Class A common stock underlying such warrants)

PROSPECTUS

Sole Book-Running Manager

Ladenburg Thalmann

The date of this prospectus is January 28, 2021.